PROTOCOL TITLE:

“Sitting Less, Moving More”: Designing a digital health intervention for Black and African American Women breast cancer survivors and their at-risk relatives (Phase II)

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1.0 Objectives

(1) The objective of the intervention development stage is to obtain formative data to guide the development of a patient-centered, family-based digital health intervention to promote increased activity in Black/African American (AA) women breast cancer survivors and their first-degree relatives through a user-centered design framework.

(2) The objectives of the pilot study are to:

a. Explore usability and perceived utility of the intervention, a mobile app, over a 4-week period; and,

b. Assess feasibility and acceptability of procedures and measures to inform future trials.

2.0 Background

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer related death in women in the U.S. and disproportionately impacts women from diverse or low socioeconomic backgrounds(1). For women who are Black, Hispanic, or socioeconomically disadvantaged, mortality from breast cancer is up to 54% greater compared to non-Hispanic white mortality(1). Additionally, the incidence of breast cancer is increasing annually for minority women, while incidence of breast cancer in non-Hispanic white women remains stable(2). Certain types of breast cancers are considered high risk, such as those that occur at a young age (<50) or those that are of extreme pathology (for example, triple negative breast cancer). These high-risk diagnoses are more common and with more disparate outcomes in Black/AA women compared to all other groups; a disparity which must be addressed.

The average woman has an approximate 12% lifetime risk of developing breast cancer, this lifetime risk nearly doubles to a 24% if a woman has a first degree relative with breast cancer, and the risk increases as multiple family members are affected. In about 5-10% of cases, inherited or genetic changes, which predispose an individual to cancer, are identified through genetic testing(3). In addition to inherited risk, often individuals have other risk factors that lead to cancer risk. For Black/AA communities this is especially true, as these communities are more likely to die of a preventable illness such as cancer, and less likely to engage in cancer preventing behaviors such as physical activity (PA)(5, 6).

Reducing sedentary time can improve health outcomes and increasing physical activity can reduce risk for cancer. Based on the poor outcomes from breast cancer diagnoses in Black/AA women and the risk associated with having a first degree relative diagnosed with breast cancer, it is critical that research efforts focus on cancer prevention within this domain. While it is known that increasing physical activity (PA) reduces cancer risk, some reporting up to a 10-39% reduction(5), there are emerging data to suggest that greater rates of sedentary time, independent of PA or body mass index(6), are associated with increased cancer risk. Any increase in PA leads to an increased preventive benefit(7) and the positive effect of PA has been noted even in the context of hereditary or familial risk(5). Specifically in a Black/AA population, recent data suggest that a high total time sitting was associated with a 27-28% higher risk for breast cancer,

independent of PA, and associations were stronger for receptor negative tumors, which are considered high risk(8). Therefore, engaging in novel interventions focused on "sitting less" and "moving more" has the potential to reduce the risk for cancer as well as other co-morbid conditions. It is known that Black/AA women are interested in digital health interventions(9), will engage in lifestyle intervention and that interventions can improve health outcomes(10), specifically if these interventions are designed to be culturally appropriate(9, 11).

Digital health solutions have been shown to effectively lead to behavior change, however significant deficits in how previous interventions have been developed and tested have limited the impact of these interventions on public health. Efforts to promote lifestyle behaviors have shifted towards evaluating technology solutions, such as computer or smart phone based (digital health) interventions. Smartphone ownership is common with 77% of US adult's own smartphones(12), and similar rates among Whites (77%) and Blacks (72%). Although ownership rates increase with level of income, 64% of those who earn <$30K and 74% of those who earn $30-49K own a smartphone(12). Review studies have concluded that increasing PA through digital health interventions can be effective among adults (13-15), including health disparity communities(16) and for cancer prevention(17).

An advantage of an digital health approach is the ability to provided individualized, tailored messages for diverse groups of adults(16) at varying levels of literacy. However, a consistent finding is that many commercially available and non-market apps *do not use* evidenced-based behavior change techniques(18), are not informed by theory(17), nor are they rigorously evaluated (13, 19). A review study found 185 available applications for breast cancer, yet only 10% involved medical experts in the creation, and 11% were evidence based(20). Shockingly, this review found that 15.7% of applications had the potential to cause harm due to a lack of evidence-based development. Therefore, the potential translational public health benefits from these innovations are lost. In summary, there is a significant need for rigorously developed and tested, theory-based digital health interventions for cancer prevention. Leveraging design strategies that place the user input at the center of the development and testing of the interventions is critical for developing effective interventions(21). This process, called user-centered design(22-24) , is imperative to the success of digital health applications (apps) for health behavior change.

Survivors of breast cancer and at-risk relatives could be the target of digital health interventions focused on reduction of sedentary time and promotion of PA. Breast cancer survivors are often encouraged to engage in health promoting behaviors, and often engage in behaviors or health recommendations due to the possibility of improving the health of others in the family. First-degree relatives of individuals with breast cancer, who have higher than average risk for breast cancer, could also be provided empathic information to understand their own risk and how reduction in sedentary time and increasing PA might play a role in breast cancer prevention. Often, the patient with cancer is the gatekeeper of this information and the key motivator in activating at risk family members towards lifestyle modification. Despite having an engaged patient population ready to engage in personal health promotion, the current model of oncology care that includes providing verbal or written education materials has not been found to

promote behavioral change(25). We are seeking to link individuals who have had breast cancer with an at risk relative in the family (a family buddy) for a family-based intervention, which is grounded in health behavior theory. Additionally, though the field acknowledges that health promotion in the context of cancer risk has the potential to impact generations of family members, none have developed interventions to reduce sedentary time at the family level for Black/AA families living with high risk. The present study will address a gap in the need for cancer prevention digital health applications that are theory-based, consider ehealth and health literacy needs, and focus on the social support components within a family-centered intervention.

In study phase I, we have completed qualitative interviews with 5 community leader key informants, 9 breast cancer survivors and 6 first degree relatives of a survivor. Information shared from our community leaders as well as the perceptions of our study participants have led to the preliminary development of the dyad based digital health intervention that we propose to evaluate further in study phase II. Qualitative interview feedback has informed our intervention materials and content, as well as process and formatting. We have also completed user testing with 6 eligible participants to get feedback on the developed intervention and to make minor iterative changes to inform the use and function of the application and study materials. We have completed the initial IRB approved phase of the study and are now seeking approval to move forward to Phase II, which will be the proposed pilot study.

3.0 Inclusion and Exclusion Criteria

(1a) Key informants (for interviews)

Inclusion criteria:

- Members of the community/advisory groups, community health centers, or faith-based network members (e.g., Pink and Black, Faces of Faith).
- English speaking adults.

Exclusion criteria:

- None

(1b) Breast cancer survivors and relatives (for interviews)

Inclusion criteria:

- Self-identify as Black or African American
- Age 18 and over
- English speaking
- Female breast cancer survivor status post curative antineoplastic treatment (except ongoing hormonal treatment) with no evidence of disease, OR a first degree blood relative (parent, child, or full sibling), of any gender, of a so defined breast cancer survivor

- Self-report ever using a smart phone

Exclusion criteria:

- Requires medically supervised physical activity (Physical Activity Readiness Question for Everyone, PAR-Q+, Question 7)
- Pregnant women

(2) Breast cancer survivors and relatives (for user testing/interviews)

Inclusion criteria:

- Self-identify as Black or African American
- Age 18 and over
- English speaking
- Female breast cancer survivor status post curative antineoplastic treatment (except ongoing hormonal treatment) with no evidence of disease, OR a first degree blood relative (parent, child, or full sibling), of any gender, of a so defined breast cancer survivor
- Self-report willing/able to download the app for testing on a smart phone
- Self-report willing/able to meet via Zoom for interview

Exclusion criteria:

- Requires medically supervised physical activity (Physical Activity Readiness Question for Everyone, PAR-Q+, Question 7)
- Pregnant women

(3) **Breast cancer survivors and relatives/“buddies”** (for pilot testing)

Inclusion criteria:

- Self-identify as Black or African American
- Age 18 and over
- English speaking
- Breast cancer survivor status post curative antineoplastic treatment (except ongoing hormonal treatment) with no evidence of disease, OR a blood relative, of any gender, of a so defined breast cancer survivor
- Self-report willing/able to participate with a blood relative in survivor-relative dyad
- Self-report willing/able to download the app for use on a smart phone
- Self-report willing/able to meet via Zoom for instructions and interview

Exclusion criteria:

- Meets exclusion criterion of the Modified Physical Activity Readiness Questionnaire (PAR-Q) (modified)
- Participated in interviews or user testing in prior phases of the study

4.0 Registration Procedures

All participants will be registered in the DFCI OnCore Clinical Trials Management System by the DFCI study coordinator. For any participant recruited and consented by a UMB research team member, the UMB research team member will provide the completed screening form and eligibility checklist to the DFCI study coordinator via the study team's Dropbox for Business folder. The DFCI PI or PD will review eligibility checklists prior to registration. For the interventional pilot study, registration must occur before the intervention begins.

5.0 Study-Wide Number of Subjects

For intervention development, we will recruit up to 38 participants: up to 8 key informants, and up to 30 breast cancer survivors and/or relatives (ideally 15 dyads) from the target population.

For pilot testing, we will recruit 20 participants (10 dyads).

6.0 Study-Wide Recruitment Methods

Key informants will be identified through recommendation of the project's advisory panel and search of relevant community-based organizations. They will be contacted in person at local advocacy meetings, by mail/email, or by phone as requested (see included study information letter and recruitment script). They will be contacted no more than 3 times for participation.

Breast cancer survivors and relatives will be recruited through in-person, web-based, and telephone methods. A study advertisement (attached) will be utilized and advertised through local advocacy and social media venues or virtual meetings with permission from the organization and distributed by key informants to potential participants. Interested participants will be able to contact the study team via email or phone and will be screened for eligibility following a script; a study specific email and telephone number will be created and managed by the University of Massachusetts Boston study team. Participants who complete an interview and provide permission to contact them again for future phases of the study may be contacted by telephone to invite their participation in the user testing phase.

7.0 Multi-Site Research

This study is a collaboration between UMass Boston (UMB) and DFCI on a funded U54 Cancer Research Partnership pilot grant and also includes an investigator at the University of Rochester (UofR). UMB and UofR have requested to rely on the DFCI IRB as the IRB of record. Approvals of the initial protocol and subsequent amendments, and

relevant IRB meeting minutes, will be shared with the UMB and UofR IRBs. As participants will be recruited from the community and thus not from the study sites, any unanticipated event requiring IRB reporting will be reported to all sites’ IRBs. Communication from the UMB and Uof R IRB will be sent to DFCI.

All study related communications will occur via weekly in-person/Web meetings with members of both study teams, or via email.

The site investigators will be jointly responsible for monitoring study progress. Dr. Marinac will oversee compliance and activities of the DFCI study staff, and Dr. Wright will oversee the UMB study staff. Dr. Underhill-Blazey is the only study member at UofR.

Accrual of up to 58 participants, completion of interviews and questionnaires, and transcribing recorded interviews and entering data, are data points that will be monitored by the site investigators on a weekly basis to ensure timely completion of the study.

Responses to eligibility screening questionnaires and attestations by research staff of participant consent will be stored electronically on the study team’s Partners Dropbox folder. The DFCI study coordinator will register each participant in a study enrollment database developed by the study team.

All data will be stored in the Partners Dropbox folder. All recordings and transcripts will be de-identified for analysis by the research team.

8.0 Study Timelines

Key informants will be engaged throughout the study up to 4 times per year (~once a quarter), including the initial interview (approximately 45 minutes), either in-person, or by telephone email, for a total of approximately 5 hours.

Breast cancer survivors and relatives (Interviews/User Testing): Dyads will participate together or separately as requested. Participation will include a one time, in-person or telephone interview. Length of study participation will be approximately 45 minutes, or as long as it takes to complete the interview conversation.

Breast cancer survivors and relatives (Pilot Testing): Dyads will participate together for a total of 5 weeks, including Baseline (Week 0) measurement and 4 weeks of intervention use with final measures in Week 4.

We anticipate primary completion by August 31, 2021.

9.0 Study Endpoints

Primary endpoints of the qualitative interview phase (interviews and user testing for intervention development) are findings that will guide the development and testing of the intervention, including: components of the intervention; culturally appropriate

messaging; means of accessing and using the intervention; and principles and strategies for identifying and accruing participants in an evaluation study.

The primary endpoint for the pilot study is feasibility. The component of feasibility include: recruitment, measurement, retention, and acceptability(26,27). Recruitment will be assessed by the number of participants screened per month; number enrolled per month. Measurement will be assessed by the completion rates at each time point divided by the number of participants enrolled at each time point. Retention will be the number who remain in the study at each assessment time point. Acceptability will be the rates of satisfaction and perceived appropriateness, attractiveness, and intent to continue as assessed by those who receive the intervention. Implementation will be the rate of delivery of the protocol and intervention to those intended to receive it. See below for *additional* metrics that our team will use to determine the feasibility of the study and its intervention.

- Recruitment. We will describe percentage of initial respondents who consent and enroll. Achieving a minimum of enrolling 3 dyads per month as an indication of feasibility of recruitment.
- Measurement and retention. We will describe completion of study assessments including wearable device. Achieving a minimum of 70% of those enrolled who complete all study data collection time-points will serve as an indication of the feasibility of the proposed study protocol.
- Acceptability. We will describe the percentage of study days in which the participant uses the Move Together app and will describe engagement with the app. Achieving a minimum of using any app feature 4 out of 7 days will provide an indication of acceptability, a subcomponent of the app’s feasibility. The acceptability of the Move Together app will also be assessed with The System Usability Scale (SUS) score. The scale has 10 items (examples: “I think that I would like to use this system frequently; I found the system very cumbersome to use; I found the various functions in this system were well integrated”) which are rated from strongly disagree to strongly agree. Scores range from 0-100; a SUS score above a 68 is considered above average (https://www.usability.gov/how-to-and-tools/methods/system-usability-scale.html.).
- Implementation. Achieving a rate of 70% of all participants completing each of these components per protocol will provide a good indication of this component of feasibility.

There are no safety endpoints.

10.0 Procedures Involved

This is a cross-sectional descriptive study using structured interviews and qualitative data analysis to develop an intervention, followed by a pilot test of the intervention with pre-/post- measures.

Key informants: We will interview Key Informants either in-person or remotely by telephone. Interview sessions (~45 minutes) will be audio-recorded, de-identified and transcribed for analysis. Field notes will also be taken. Participants will complete a short demographic questionnaire. We will contact Key Informants up to 4 times over a year

(~once per quarter, including the initial interview) to obtain feedback and guidance about the study's endpoints. We anticipate that these interviews/contacts will amount to ~4-5 hours in total per participant for the year. Key Informants will be given an incentive of $300 for the year as a thank you for their time.

The primary goal of engaging with key informants will be to identify: 1) an acceptable and feasible approach to identify and engage at risk family members in a family-based intervention; 2) how to best support the breast cancer survivor to motivate and recruit one of their family members to participate in a "sit less, move more" intervention; 3) the challenges and barriers to, and benefits of, sitting less and moving more; 4) the digital health intervention components that are culturally acceptable and address identified challenges.

Breast cancer survivors and relatives: Phase I A (Interviews): Procedures will include a one-time interview by telephone, and demographic questionnaire. Consent will be obtained prior to conducting audio-recorded interviews. All interview data will be de-identified for analysis. Participants will receive a $30 Amazon or Target gift card (their choice) to thank them for their time.

We will conduct interviews with about 10 women who are survivors after curative treatment for breast cancer. The focus of these interviews will be to gain insight into the participants' attitudes and perceptions about "sitting less" and "moving more", e.g., perceptions of the health benefits, family dynamics related to healthy behaviors, cultural factors related to these behaviors, preferred delivery channel for communication (e.g., text, Web, print), and frequency of contact with the app and family buddy. These insights will inform the components, content and cultural aspects of the family-based intervention and the role of social support. We will also recruit about 10 first degree relatives of individuals with breast cancer meeting the previous criteria to independently complete interviews. The survivors and relatives will be interviewed separately or together, per their preference. We will also ask the participants for their permission to contact them after the interview if we have follow-up questions, e.g., we need to ask a clarifying question, and assess their interest in providing feedback about study findings, or to invite their participation in future research.

We will also ask participants if we can contact them in the future to invite them to a community meeting where we share the results with those who are interested.

Demographic questionnaires will be collected securely via Dropbox (Partners Business version) or REDCap (Partners) or verbally by phone per preference of the participant.

Phase IB (User Testing): About 10 survivor/relative participants who completed interviews and gave permission to be contacted again for further research will be re-contacted and consented for a second session – or new participants may also be recruited and consented up to a total of about 10 participants - to provide feedback on the intervention app in development. The sessions will be up to 45 minutes, conducted using UMB's HIPAA-compliant version of Zoom, and audio recorded externally.

After obtaining consent, a research assistant will arrange for the participant to download the app and use it for one to a few days before the interview. The app is being developed using PiLR Health software, an extensible platform for research and intervention

development in an ecological momentary assessment (EMA) framework, in which a participant may be prompted to repeatedly report what they are doing in their daily life context and receive tailored feedback and messaging to promote health behavior change. Depending on the app version and which features are being tested, a participant might be prompted, e.g., to answer a few questions about physical activity goals, then later allowed to report their activity, or queried if goals were met, or if not, what the barriers were, or may be able to view visualizations of activity data that they entered, or receive motivational messages via text. In addition to their use of the app, during the interview session, researchers may present a series of screenshots via Zoom of the app in development, other apps (such as, FitBit), or a linked educational website to illustrate potential features, messaging, and look of the app, and will ask participants for their impressions and suggestions.

A recruitment script, interview guide, and sample screens and prompts for this part of the research are attached. As the design process is iterative and responsive to participant feedback, new screens and prompts will be developed and variations on the questions in the interview guide will be added as the sessions continue. Individual iterations will not be submitted for IRB review during the iterative development. Of note, only feedback provided in the interview session will be stored and used for app development; PiLR Health software provides functionality for researchers to monitor and store data related to participants’ use of an app or responses to questions, but no data will be stored or used for this phase of the study. Participants will be able to download and use the app without providing identifiers, and security of the software has been reviewed and approved by DFCI Information Security Officer Mark Tomilson via the MGB Vendor Information Security Plan (VISP) process.

Phase II (Pilot Testing):

Participants in the pilot study will participate as members of family-based dyads (n=10 dyads). One member of each dyad will be a breast cancer survivor and one will be a blood relative. Either person can respond to the study recruitment postings. A research assistant will remotely (as above) provide a study information sheet containing all elements of consent, describe the study, obtain informed consent, and screen them for eligibility following attached scripts. The participant will then invite a relative to contact the study team for consent and eligibility screening. When both participants have consented and been determined eligible, they will be scheduled to begin the study.

The intervention and study are designed for breast cancer survivors and at-risk relatives. However, in case it is not feasible to recruit sufficient family-based dyads, if an interested participant does not have a relative they are willing and able to have join the study with them, we will ask if they would like to be placed on a wait list in case the eligibility criteria for the study would be broadened (IRB amendment would be submitted).

Baseline: To begin the study, dyad participants will be scheduled for a joint HIPAA-compliant Zoom meeting with a research assistant, who will send a baseline package in advance to each participant by FedEx or US Mail. If it is not possible to meet at the same time, participants will be scheduled to start within no more than 3 days of one another. In the baseline Zoom session, the research assistant will instruct participants to open their

baseline package and remove the activPAL device/instructions and will be instructed in the baseline, 1-week duration (Week 0) activPAL wear protocol (see attached instructions). The activPAL device is a research grade wearable for monitoring physical activity (https://www.palt.com/). Research study staff will configure the activPAL device to collect data using a study ID number only. Participants will also complete the baseline questionnaire via REDCap during Week 0. All instruments selected for the baseline questionnaire are intended to serve as a reference measure for a future efficacy trial. Therefore, they are primarily used to gather information on cultural relevance and appropriateness, which we will assess quantitatively by %completion rate (>70% is deemed acceptable) as well as qualitatively using debriefing interviews. Additionally, a distal goal of our study is to reduce cancer/health disparities in minoritized communities. It is important to describe the racial and ethnic characteristics and social economic factors that are known social determinants of health. To fully describe our sample, we will gather self-reported demographic and social economic questions.

If participants are not able to use REDCap, the research assistant will schedule a telephone call to collect the baseline questionnaire.

Week 1 Start: A second Zoom session will be scheduled at the beginning of Week 1. Participants will be instructed how to remove and return the activPAL to the research team to download data and re-charge the devices. Participants will also at this time be instructed how to download the PiLR EMA app to their smartphone and will be given user IDs and passwords to access the MoveTogether Boston app on it. The research assistant will direct them to the printed PiLR EMA privacy policy included in their baseline package (attached; also accessible electronically at any time through the app “Settings”) and will be advised that the app does not collect any private information or identifiers (including device ID) from their phone; they will also be advised again not to include PHI in the text fields or dyad partner (“buddy”) messages that they type into the app so that their use remains anonymous.

In the same Zoom session, participants will be instructed in how to begin wearing the Garmin vivofit® 4 (https://buy.garmin.com/en-US/US/p/582444) that they can use throughout the intervention and keep when the study ends. The Garmin device is a consumer-oriented fitness tracker. Participants will be shown in the device instructions (attached) where it explains the limited use of the device possible without creating accounts with the Garmin company, which would collect user data and be Participant to the company’s terms of use and privacy policy. Participants will be told that for the purpose of the study, they do not need to create accounts but can use the Garmin watch independently of account registration and manually enter information from it (e.g., number of steps in a day) into the Move Together PiLR app. If they choose to create Garmin accounts, it is at their discretion and the study team cannot provide technical support for doing so.

Week 1-4 (Intervention): Participants will use the Move Together app and Garmin trackers during Weeks 1-4. The participants will be encouraged to interact with the app every day but the study team will not personally contact the participants during the intervention period. The participants will be invited to use the app as follows: Each day the app will send a push notification in the morning to remind the participant to set a

movement goal for the day. Once the participant is in the app, they can visit any of its content as they wish. During the day, a reminder will be sent to send a message to their buddy/dyad. At the end of the day, a push notification will be sent to the participant about reporting his or her steps and progress made on the goal set for the day. These notifications can be turned on or off by the research team or the participant if they wish not to see them.

The Move Together app allows users to set daily goals for increasing physical activity and decreasing sedentary time, track progress on goals, message their buddy, and access external educational infographics and other resource links hosted on a Wix website maintained at UMass Boston, which uses a hidden URL and does not require authentication to access (see attached Move Together Screenshots, Infographics, and Resource List). The Move Together app does not collect or store identifiers on the user’s phone, and users will not be required to enter identifiers as their login credentials (users will be provided anonymized credentials which will be recorded in the study enrollment log). The app will track usage including frequency and type of task completed on the app and will store data that users enter (such as the number of steps taken in a day, or the content of a text message). These data will be analyzed to understand usage patterns and evaluate utility of app features.

The purpose of the Garmin activity tracker in this study is for participants to track their steps and sedentary time. They may also use the basic device features without creating an account and sharing identifiers: progress bar that compares their number of steps each day and basic clock. Participants will be shown how to use the Garmin devices without creating accounts (see attached Garmin Instructions). If they choose to create accounts to synch their watches to computers/phones and use advanced features, they will be Participant to the manufacturer’s terms of use and privacy policy, and we will not provide technical support for those advanced uses.

Week 4: Participants will complete a second REDCap questionnaire and wear the activPAL tracker for 1 week as post-intervention measures.

Participants will also meet with a member of the research team for 30-minutes via DFCI or UMB HIPAA-compliant Zoom to complete an individual structured interview about their experience in the study and with the app (see attached Pilot Study Interview Guide).

Table 1. Summary of pilot study procedures and measures

	Week 0	Weeks 1-4	Week 4
	Baseline	Intervention Pilot	Post-Intervention
Demographic questionnaire (REDCap)[1]	X		
Physical activity[2], sedentary behavior[3], quality of life[4], and social support for exercise[5] questionnaires (REDCap)	X		X
App usability[6], utility and acceptability[7] questionnaires (REDCap)			X
activPAL wear protocol	X		X
Use of Move Together app with Garmin activity tracker watch		X	
PiLR app platform collects data on frequency of use, tasks completed (e.g., goal setting, messaging), content of messaging		X	
Semi-structured qualitative interview about experience with the app and study participation (Zoom)			X

[1]Demographic questions drawn from standard measures including from the U.S. Census Bureau, Pew Surveys, and financial toxicity measures.
[2]Physical activity assessed using the Global Physical Activity Questionnaire(28).
[3]Sedentary behavior assessed using the Sedentary Behavior Questionnaire(29).
[4]Quality of life assessed using the PROMIS Global Health Scale v 1.2(30).
[5]Social support for exercise assessed using a measure developed by Sallis and colleagues(31).
[6]App usability assessed using the mHealth App and System Usability Scales(32).
[7]Utility and acceptability assessed using the App Acceptability and New Information/Utility questionnaire, developed by the study team (see Appendix).

11.0 Data and Specimen Banking

N/A

12.0 Data Management and Confidentiality

Phase I

No power analysis will be conducted for this descriptive study. The number of participants is based on common practice in qualitative research.

Interview data will be analyzed using content analysis in NVivo® v11 software (QSR International). Questionnaire data will be summarized using descriptive statistics.

Interview recordings will be electronically de-identified using Sony Sound Forge Audio Studio® v10 software and stored on a secure Partners Health Care server that requires user authorization and authentication for access and will be limited to the study team. Recordings will be transcribed, and transcripts will be analyzed with only a study ID number. Recordings will be deleted at the end of the study.

Phase II

No power analysis was conducted for the pilot study. We have proposed a sample size of 10 dyads, which is consistent with previous literature(33,34), as well as practical within the scope and timeline of the study funding.

For our pilot phase the following self-reported measures will be utilized:

Sedentary time will be assessed with a thigh worn device, activPal3, the most sensitive and valid objective measure of sedentary time.

The measures in Table 1 were included as potential endpoints or covariates to include in future larger trials. In this study we will ensure that the measures are appropriate, accessible, and sensitive to this population. This will be assessed in our end of study exit interviews, as well as in reviewing patterns of data completion and missing data.

Data Analysis Plan.

All enrollment, attrition, and completion data, and self-report survey measures will be summarized using descriptive statistics (i.e. frequency, percentage, mean). We will evaluate single item responses as well as survey scores as presented in the user manual. Patterns of missing data will be described for both self-report and objective measures. Exit interview data will be thematically content analyzed by the study team, including trained students. A summary of the study outcomes will be circulated to the Advisory Panel of community leaders. All findings will inform future work within a larger powered trial.

Data Confidentiality. A single password protected file will link participant identifiers to study ID numbers during the research to manage logistics and assure organization and quality of the final data. When analysis of the primary study outcomes is completed, the linking key will be removed.

Data and the participant list will be (separately) electronically stored after the study is complete per SOP: Record Retention for Completed Research *(RCL-101).*

The study team is comprised of experienced researchers trained in human Participants’ protections. The study staff and all research activities will be monitored by the PIs. The PIs and Project Director will train all study staff in procedures for maintaining participant confidentiality and securing data. All members of the research team will be responsible for immediately reporting breaches of confidentiality or data security to the PI, local compliance office per institutional policy, and the IRB.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

The PIs and Project Director will monitor data on device usage, text comments in the app, outliers in reported physical activity and sedentary behavior, questionnaire responses, calls to the research team, and responses in the interview for indications of privacy loss, injury or distress. All subject-submitted data will be reviewed by the study team weekly, and weekly project meetings will be used to debrief. Safety issues will be reported to the review board per DF/HCC policy.

14.0 Withdrawal of Subjects

Participants will be able to withdraw at any time with no impact on their current or future medical care or relationship with the UMass Boston – Dana-Farber/Harvard Cancer Care Partnership.

15.0 Risks to Subjects

We anticipate the study to be no greater than minimal risk. The questions that we ask are not intended to be sensitive in nature. However, if a study participant is upset or distressed during the study, the interviewer will ask if the participant would like to stop the interview and will refer the participant for follow-up to local resources as necessary. Participants will also be able to skip any questions that they do not feel comfortable answering.

Another potential risk is that, in the course of recruitment and screening, e.g., explaining eligibility criteria, a potentially eligible breast cancer survivor or relative may learn or come to understand their increased cancer risk in a way that had not previously understood it, and may become distressed as a result. If this happens, the study team member will refer the participant to local resources (i.e. local genetic counseling services) for follow-up assessment and discussion of cancer risk and potential genetic testing. The study team will facilitate providing information about local genetics resources.

In the Pilot Study, there is additional minimal risk of loss of privacy by using wearable devices and a mobile app. We have selected the devices and app platform and designed instructions to participants to minimize risk (see Section 9 above, attached participant device Instructions, Pilot Study Information Sheet and Pilot Study Recruitment Script/Consent Form).

In the Pilot Study, there is additional minimal risk of physical injury from gradually increasing physical activity. We will use the Modified PAR-Q (modified) to screen out participants who do not meet criteria to safely begin a physical activity program (see attached Pilot Study Screening Form) and also will tell participants that the study does not require that they do vigorous physical activity but instead the intensity of activity to which they are accustomed and is comfortable.

16.0 Potential Benefits to Subjects

There are no benefits of participating in this study. Participants will be informed that there are no direct benefits, but that their participation may help us design a

health promotion intervention for breast cancer survivors and their first-degree relatives, which could benefit others, and design a future study.

17.0 Vulnerable Populations

Vulnerable populations will not be included.

18.0 Community-Based Participatory Research

This study is not community-based participatory research.

19.0 Sharing of Results with Subjects

Any publications resulting from this work will be disseminated to the community organizations and participants as requested. We anticipate inviting the research participants to a one-time event to present the findings of this study. The data will be presented in aggregate and no identifiable information will be presented.

20.0 Setting

Participants will be recruited through local community organizations and key informants by distributing flyers/advertisements both in person or online and through word of mouth. The online advertisement will be posted on any social media sites with the permission of the hosting community organization.

Research will be conducted in the community virtually and interviews will be conducted by telephone. Survivor/participant user testing interviews for Part B and Part C pilot study sessions will be conducted via UMB’s or DFCI’s HIPAA compliant Zoom; participants can connect using their own desktop, laptop or tablet device, or smart phone.

21.0 Resources Available

The study team is well equipped to complete the proposed research. Dr. Marinac at DFCI will have all resources available through the Phyllis F. Cantor Center and Population Sciences to conduct the study and provide study oversight, including research assistants, coordinators, and project directors. The Cantor Center has all software to conduct the study, including NVivo and software to de-identify audio files, and transcription will occur with trained transcriptionists, either professional or students from UMB. Dr. Wright at UMB will have the support of student research assistants and telecoms to host remote meetings and facilitate recruitment. Dr. Underhill-Blazey was previously faculty at Harvard Medical School and served as overall PI of nine protocols under the DFCI IRB. Her effort will be the only resource from UofR.

Each member of the team is experienced in user-centered design and qualitative methods, specifically community based qualitative research.

We anticipate no recruitment challenges based on previous research experience with the community advocate organizations. The study team will allocate time

resources to conduct the study per the timeline. The study team will be available to triage any psychosocial concerns or distress that may arise during the study.

22.0 Prior Approvals

N/A

23.0 Recruitment Methods

Local recruitment is as described above in section 5.0 Study Wide Recruitment, as all participants will be recruited from the community, not clinical sites. Participants will be recruited through online or telephone methods, using letters and advertisements that are attached. We will ask interested individuals to contact the study office for more information about the study and to find out if they might be eligible. A study team member will follow up to explain the study and obtain informed consent, and a payment will be made after completion of the interview.

24.0 Local Number of Subjects

For intervention development, up to 38 individuals – up to 8 key informants, and up to 30 patients/family members (ideally dyads) – will be recruited and enrolled.

For pilot testing, 20 participants (10 dyads) will be recruited and enrolled.

Institutions will register eligible participants from the pilot study in the Clinical Trials Management System (CTMS) OnCore as required by DF/HCC Policy REGIST-101.

25.0 Provisions to Protect the Privacy Interests of Subjects

Procedures include: the screening and enrollment logs will be kept in a secure, encrypted database that requires authenticated login and password protection; consent forms will be locked in study offices; all audio recordings of interviews will be de-identified (using digital voice editing software) prior to transcription; transcripts will identify participants only by a study ID number; individually identifiable private information will be accessible only to study staff who are trained in the protections of human subjects and study procedures and IRB approved.

26.0 Compensation for Research-Related Injury

N/A

27.0 Economic Burden to Subjects

There are no costs to participating in the research. If the participant prefers an in-person interview, we will pay transportation costs with a transit or taxi voucher.

28.0 Consent Process

Key informant participants will receive an information sheet that includes elements of consent through both the mail and email letters (attached). In a follow-up phone call, a study team member will explain the study and all elements of consent, answer any questions, and obtain consent to participate in the interview prior to engaging in study procedures. Participants will be asked if they agree to be audio recorded; if they prefer not to be, they will be told that an additional research assistant will participate in the interview to take notes. The mode, date and time of the consent discussion, and whether the participant agrees to be audio recorded, will be documented in the enrollment database kept by the study team. When the interview starts, the interviewer will confirm agreement to being recorded.

Breast cancer survivors and relative participants will be screened by telephone to ensure that they meet eligibility criteria and a study team member will explain the study procedures and all elements of consent. A study information sheet will be provided electronically or by mail to all participants. Participants will be able to ask questions and given time to consider participation. Their consent to participate, and if so, to be audio recorded, will be documented by the study team member on the Screening/Consent Form (attached) and in the study team’s Screening/Enrollment Log.

29.0 Process to Document Consent in Writing

For the **Key informants**, we request a waiver of written documentation of consent as they will be stakeholders, experts and community leaders focused on improving breast cancer health disparities in Black/AA women.

For the **breast cancer survivors and relatives**, we request a waiver of written documentation of consent to minimize the burden of mailed consent during the COVID-19 pandemic. The study team member who consents the participant by telephone will complete contemporaneous documentation of the consent discussion.

30.0 Drugs or Devices

N/A

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