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1. Title
Survivor mHealth Pilot Study (H00023545)

2. External IRB Review History*
None.

3. Prior Approvals:
There are currently no conflicts of interests.

4. Objectives*
The purpose of this pilot study is to test a previously developed mobile health system in a new population, cancer survivors, with the goal of refining the program and setting the stage for a larger future trial. We would like to test the feasibility of using a wrist-based wearable (Fitbit) and smartphone application dyad with survivors, including seeking feedback on survey data collection and message prompts delivered in the application. We will also seek feedback from our clinical partners to understand implementation of referrals to a digital health program and perceptions on accessing patient-generated health data from these programs.

The overall aims of this study are to:

1) Test the feasibility of deploying a wrist-based wearable device (Fitbit) and smartphone application dyad to cancer survivors aged 18 years of age or older.

2) Obtain qualitative feedback on the program acceptability, including mobile questionnaires and message content used for push notifications sent within MyDataHelps.

3) Obtain qualitative feedback from Cancer Center providers and clinic staff on implementing referrals to digital health programs and attitudes/preferences toward receiving and accessing patient-generated health data.

5. Background*
Cancer survivors have an increased CVD (1.7-18.5 fold) and mortality (1.3-3.6 fold) risk.[10,11] Physical activity is a modifiable CVD risk factor across cancer diagnoses.[12,13] Yet, few survivors are active during (<10%) and after treatment (20-30%).[13,14] The American Heart Association recommends providers deliver physical activity referrals to prevent CVD in survivors;[11] however, providers report uncertainty in delivering these referrals.[15] Further, acknowledging an individual's unique perspective, and offering choices rather than referrals to one singular program have been shown to be more effective.[50,51]

A number of physical activity programs exist for survivors, including survivor-specific LIVESTRONG at the YMCA, an in-person community-based program shown to be efficacious at increasing survivors' physical activity levels.[16] LIVESTRONG is offered at >700 YMCAs nationwide, though is still not widely available to all geographic locations in the US.[3,16] To address geographic locations (and in-person program restrictions due to COVID-19), other options are available. Virtual group programs have appeared as options preferable to some survivors, allowing them to still have the social support they seek in a group format but the convenience of doing a program from one's own home.

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In our prior work, we worked with UMass Medical Cancer Clinic staff to conduct referrals to two group programs, LIVESTRONG (in-person) and Fit Cancer (virtual). Staff referred patients to the program of their choice at their survivorship care planning visits. From 3 sites, 7 of 17 clinic staff agreed to participate, referring 13 participants over 10 weeks. Of those referred, 7 enrolled in LIVESTRONG and 5 in Fit Cancer. During follow-ups, both survivors and clinic staff reported excitement about being able to choose from multiple physical activity programs. However, we found survivors also wanted a non-group format digital health program option. Survey data of survivors revealed 51% (n=31) of participants reported a preference for digital health support for physical activity, even after the COVID-19 restrictions are removed.[5] Digital health programs can be effective in promoting physical activity and reducing participation barriers.[17] Thus, in this study we propose to test a program developed by co-mentor Dr. McManus, that uses Fitbits to provide self-monitoring and tailored feedback. [6] Based on results, we will incorporate this program as an additional referral choice for survivors in a future trial.

Data monitoring systems that collect physical activity and health data from a wrist-based wearable device and smartphone application surveys have primarily consisted of Fitabase and CareEvolution. Both are used extensively by companies, researchers, and more to collect and display large amounts of data. Fitabase has an extensive overhead cost, while CareEvolution on the other hand, could potentially cut the cost of Fitbit data monitoring significantly, which would allow for participant data to be tracked over longer periods of time and would increase the feasibility of future longitudinal studies using Fitbits to monitor health and physical activity data. CareEvolution allows users to create and administer mobile surveys to participants. My collaborator, Dr. David McManus, developed and tested a data monitoring system with the help of CareEvolution. Through his work with CareEvolution and Fitbit, they were able to get the CareEvolution study team the same level of access to raw Fitbit data as Fitabase has. He then further tested the system in a larger multi-site trial (the RURAL Study).

It is integral to test technology systems with target populations, including our population of cancer survivors. Our aim is to test the feasibility of using this wearable device and application-based program, while soliciting feedback on ways to further refine the program to make it more specific to cancer survivors. This will include personalization of the push-messages participants receive within the app, with the goal of increasing survivor's physical activity levels. We hope that our findings will lead to testing of this technology program as a choice in a larger population of cancer survivors.

6. Inclusion and Exclusion Criteria*

Study Population

The study population will be derived from pre-existing relationships with community stakeholders and UMass clinic providers who work directly with cancer patients. We will also draw on survivors who took part in our prior trials and indicated wanting to take part in future research with us. We will only include English speaking participants because as of right now, the app is only available in English.

<u>Aims 1 and 2</u>

Inclusion Criteria:

1. Past cancer diagnosis

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2. At least 18 years of age
3. Capacity to provide informed consent
4. Medically cleared to perform physical activity (as noted by PAR-Q form or physician's clearance)*
5. Owns a smartphone

*Medical clearance will be sought with patient's provider if needed (see smhealth_med_clearance)

Exclusion Criteria:

1. Is a prisoner
2. Non-English speaking
3. Is unable to provide consent
4. Under 18 years of age
5. No prior cancer diagnosis
6. Does not own a smartphone

Aim 3

Inclusion Criteria:

1. Are a current UMMHC Cancer Clinic patient navigator, oncologist, radiologist, or cardiologist
2. Consent to participate

Exclusion Criteria:

1. Not currently employed at UMMHC
2. Not involved in direct treatment of care coordination of cancer patients

Vulnerable Populations

Children

Children will not be included in the study population.

Prisoners

Prisoners will not be included in the study population.

Adults Unable to Consent

Adults unable to consent will not be included in the study population.

Pregnant Women

Pregnant women will be included in the study population.

7. Study-Wide Number of Subjects*

We will include up to 50 participants made up of cancer survivors, providers, and clinic staff.

8. Study-Wide Recruitment Methods*

N/A. This is not a multi-site study.

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9. Study Timelines*
The overall project timeline is described in the table below (Table 1):

Table 1. Project Timeline

	Apr	May	June	July	Aug	Sep
IRB, recruitment of participants	**X**	**X**				
Wearing of the devices and completion of surveys to track data, transmission of the device data to the servers		**X**	**X**	**X**	**X**	
Data Analysis and data transfer				**X**	**X**	
Qualitative Interviews				**X**	**X**	
Study conclusion and write-up						**X**

The study is planned to take place over the course of six months but will be extended if need be until all goals are achieved. Primary analysis is expected to be complete by the end of six months.

Duration of an Individual Subject's Participation
Individual subjects in the Aim 1 pilot are expected to participate for no more than 90 days in the study. Aims 2 and 3 consist of one-time interviews.

10. Study Endpoints*
Primary Outcome Measure: To assess the feasibility of a wearable device and smartphone app digital health program in cancer survivors.

Secondary Outcome Measure: To assess usability, physical activity, and quality of life health outcomes measures. We will also qualitatively assess 1) participant experiences and improvements to be made to the program, and 2) provider and clinic staff perceptions of implementing referrals to digital health programs and accessing patient-generated health data. medical providers/clinic staff .

11. PROCEDURES INVOLVED

METHODS
Population: We will include a total of up to 35 cancer survivors and 15 providers/clinic staff.

Setting:

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This study will mainly take place at the University of Massachusetts Medical School, with remote recruitment allowing for participants to partake in study activities outside of the institution. Analysis of the Fitbit and MyDataHelps survey app data will be taking place using secure medical school computers, in a secure office space. Additionally, data from the Fitbit and MyDataHelps survey app will be transferred from the Fitbit and MyDataHelps to CareEvolution and UMMS via secure SFTP (Secure File Transfer Protocol) servers that are compliant with HIPAA requirements. The SFTP server ensure that only intended authorized personnel can receive data and that transmissions are protected with strong encryption algorithms.

Aim 1 Procedures:

The research assistant (RA) will send eligible participants a secure inquiry email that will contain information about the study and ask if they would be interested in participating. If participants are interested in joining the study, they will be instructed to click a secure REDCap link in the inquiry email. This link will direct them to an electronic consent form. If the individual would like to participate in the study, they will provide their electronic signature. They will also have the option to do this over the phone/Zoom guided by research staff through the REDCap form or a consent form that was emailed to them. They will then be able to provide verbal consent with research staff if they are unable to access the REDCap online form.

All participants will receive a Fitbit to keep as part of their compensation for participating. The participant may also choose their preferred way of delivery of the device such as in-person or through the mail. Once the consent form is completed, the RA will give or send the participant their study devices. Participants will also receive instructions on how to set up their devices and link their Fitbit via a secure email after we give them their device(s). In these instructions we will inform the participant how to create and log into the smartphone applications and use the device(s). Participants will also be instructed to wear their Fitbit for a total of 3 months.

The participant's Fitbit will receive automated Fitbit push notifications (See Survivor mHealth Pilot Push Notifications.xlsx) to promote adherence (e.g., "Keep it up"). The participant's smartphone will also receive push notifications from MyDataHelps to promote adherence to the study surveys and Fitbit. If participants are experiencing technical challenges or difficulties adhering to study protocols (e.g., syncing Fitbit, completing surveys), we may then contact participants by phone to troubleshoot potential issues. Overall, our main goal of the pilot study is to determine feasibility in this population using these devices, while obtaining feedback we can use to refine the study before launching a larger trial in cancer survivors.

Furthermore, study participants will download two apps onto their phone: Fitbit and MyDataHelps. The apps can be downloaded through the Apple App Store or Google Play Store. Instructions will be provided to participants on how to download and navigate these apps. The instructions will also include a unique study ID number for each participant. When a participant is signing up for the apps, they will use their assigned study ID as their first name. To further maintain confidentiality, all participants will be assigned the same last name "MHEALTH" when signing up for these apps.

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The study ID will be used for data exports so that participants' names are de-identified. Participants may also choose if they would like to use their personal email address or a study generated email address to register for the MyDataHelps and Fitbit app. Through the MyDataHelps app, participants will complete a set of surveys at 24 hours after their enrollment, 1 month, and 3 months after enrollment (Table 2). The following surveys will be deployed to study participants: Quality of Life Health Status (FACT-G), MARS (app usability), and Physical Activity. Overall, the main purpose of these surveys is to make sure we can successfully obtain data and to receive feedback on the usability of the devices and app. Subjects will not be explicitly told that they should explore the MyDataHelps app however, it is anticipated that subjects will become familiar with the app and explore its features given that their Fitbit data will be linked to the app and that their surveys will appear here as well.

Participants will also receive push notifications on the day of their enrollment and reminders for follow-up surveys. These notifications have been submitted for review and have been approved by the IRB. These adherence notifications have been submitted for review and have been approved by the IRB.

We will link a participant's Fitbit device into the MyDataHelps app. Once participants have registered for MyDataHelps and have linked their Fitbit devices, their raw Fitbit data will be transferred to CareEvolution (Table 3). The CareEvolution team will generate and update a data dashboard once or twice per day to allow the UMMS team to monitor participant adherence.

Once the participant has completed all the tasks required for the study, they may keep their Fitbit.

Aim 2 Procedures:

Upon completion of the study tasks, we will email participants to offer an option to take part in a 30-minute semi-structured telephone/Zoom interview. Participants who choose to take part will be compensated with a $25 gift card within 2 weeks of the interview completion. The interview will consist of questions asking their perceptions of the program overall, as well as asking them ways to improve the current list of messages they received within the app (See Survivor mHealth Follow-up Interview Guide.docx). We will schedule these interviews via Zoom or telephone at their convenience.

Aim 3 Procedures:

Once a participant contacts the study via email or phone, we will set-up a time to perform a consent and semi-structured interview via web-based video call (Zoom – See Data Management below) or telephone. We will interview UMMHC medical providers, with a purposeful sample of at least one navigator from the Hematology/Oncology and one from the Breast clinic, as these are two of the largest clinics at the hospital. Participants will be asked to complete a 30 minute interview scheduled at their convenience to discuss implementing physical activity referrals to digital health programs into clinical workflow, along with preferences for reeving those data. If on Zoom, we may screen share with participants to show them examples of data dashboards they could see containing patient generated health data (using de-identified data

from the CareEvolution platform). We will interview UMMHC medical providers, with a purposeful sample of at least one navigator from the Hematology/Oncology and one from the Breast clinic, as these are two of the largest clinics at the hospital.

Table 2. CareEvolution Survey Data Elements

Overview (cumulative enrollment data)	Domains
Participants	Baseline Enrollment Monitor
Enrollment date	
Total # Participants Eligible	
Total # Participants Enrolled	
Total # Participants by Site	
Age	
Gender	
Type of Phone:	
Android	
IOS	
Fitbit provided	
Surveys delivered at baseline (24 hours after enrollment)	Survey Wave 1 (Physical Activity, FACT-G, MARS (app usability))
% complete	
% incomplete	
% overdue	
% closed	
Average days to complete survey	
Average time (sec) spent in surveys	
Steps (number of clicks)	
Surveys delivered at 1 month	Survey Wave 2 (Physical Activity, FACT-G, MARS (app usability))
% complete	
% incomplete	
% overdue	
% closed	
Average days to complete survey	

Average time (sec) spent in surveys	
Steps (number of clicks)	
Surveys delivered at 3 months	Survey Wave 3 (Physical Activity, FACT-G, MARS (app usability)); Qual interviews
% complete	
% incomplete	
% overdue	
% closed	
Average days to complete survey	
Average time (sec) spent in surveys	
Steps (number of clicks)	
Surveys delivered overall	Surveys Overall
% complete	
% incomplete	
% overdue	
% closed	
Average days to complete survey	
Average time (sec) spent in surveys	
Steps (number of clicks)	

Table 3. CareEvolution Fitbit Data Elements

	Adherence Metrics
	Any participant data
	Last device sync
	More than 14-days since last sync
	Total Days Worn (avg.)
	Wear Time (avg. minutes/day)
	Summary of Variables
All Heart Rate Data	Heart rate (daily average)
	Resting heart rate (daily average)
	Resting

	Minimum
	Maximum
All Step Data	Steps total (daily)
	Steps average (over 1 week)
	Steps average (over 1 month)
All Sleep Data	Sleep (avg. hours/night)
	Wake
	REM
	Light
	Deep
All Physical Activity Data	Physical Activity (avg. minutes/day)
	Light
	Moderate
	Intense
All Calorie Data	Calories (avg./day)
	Floors (avg./day)

12. Data and Specimen Banking*

N/A

13. Data Analysis and Management*

Data Analysis

Quantitative data (Aim 1) collected from surveys will be analyzed by calculating aggregate descriptive statistics (due to the small sample size) using STATA version 15.

Qualitative interviews (Aims 2 and 3) conducted at the conclusion of the trial will be recorded, and notes taken by the interviewer. Notes will include no identifying or personal information and only ease of use of the technology system. These notes will be kept on a secure server with recording files and added to the interview transcription data. The transcribed interview data will be analyzed and summarized according to standard comprehensive, thematic qualitative analysis methods. Initial coding is primarily descriptive in nature, with questions from the interview guide serving as the framework for the prefigured coding structure. With an orientation toward framework analysis, a more inductive approach is then utilized in the second phase of coding. Categories that emerge from the data form the broader thematic framework, which is then

applied to all interview transcripts. These methods may be enhanced in certain sections/parts of the interview using a data management software program, N'Vivo (QSR International). The program uses an organizer indexing system for coding, categorizing, searching, retrieving, attaching analytical memos, and creating conceptual relationship networks in textual data that has been taxonomically coded.

Data Security

In this pilot study, wrist-based wearable devices will be used to collect activity, heart rate and sleep data. We are using previously established and IRB-approved methods as in the McManus mHealth Pilot Study (IRB # H00020228).

The device data will be de-identified since all data will be stored under a participant ID. Servers will be securely housed at the UMMS Data Center that will limit information to only those in the Information Technology (IT) professionals with a functional and role-based need and with proper electronic identification. Additionally, Standards and Trust Security Principles (TSP) as it relates to the physical security attributes of the Security Principle for the UMMS Data Center as set forth in TSP 100. A SOC II, Type II external audit and report is completed every 18 months with the most recent occurring in June 2020.

Research staff at UMMS will have a login name and password to access participant data, including adherence, physical activity, and survey data monitoring. Only study staff will have access to the participants' secure online database accounts. UMMS also has vulnerability scans that are conducted with the designated SCAP-approved vulnerability tool regularly. Devices are also adhered to the NIST Publication 800-123.

Mobile survey data and Fitbit data will be collected using a CareEvolution application called "MyDataHelps." Participants will sign an electronic consent form by entering their name and signature. Mobile survey responses will be de-identified since all data will be stored under a participant ID and will be transmitted to the secure CareEvolution server. Data transmitted to CareEvolution will be de-identified when extracted by the UMMS team. Information collected by the CareEvolution app will be securely stored on CareEvolution servers in the United States, or on servers owned by third party service providers that CareEvolution contracts with to securely store information in the United States. Data will be securely sent to UMass staff within one-week. The following link contains CareEvolutions security guidelines: https://rkstudio-customer-assets.s3.amazonaws.com/CareEvolution/MyDataHelpsPrivacy.html
The following security protocols will also be applied to all data: physical protections – all recordings and data will be stored on secure servers behind firewalls at UMMS. Additionally, UMMS has implemented a segregated environment for enhanced protection of systems that contain sensitive data. The data is housed and maintained outside of the regulated customer hosting environment which will in turn reduce the risk of cross contamination. The regulated environment is securely architected and supported by structured vetting and approval processes prior to access or system provisioning. All administrative access requires SSL VPN which utilizes multi-factor authentication.

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All hard copy files will be locked in secure cabinets; logical protections – all recordings and data will be password protected and/or encrypted; and access protections – access will be granted to data on a need to know basis only.

All study staff that will be collecting or handling participant data will be trained in human subject procedures, confidentiality, and privacy protection. All investigators and project staff are required to receive and complete Human Subjects and HIPAA training. All PHI data acquired from EHR will be securely stored in REDCap and only accessed by training study staff.

Study ID numbers will be included in the research data set in order to protect participant confidentiality and any data transferred by CareEvolution will be de-identified.

Once the study is complete, we will strip our research data of all identifiers and only maintain the limited database for any subsequent analyses that may become necessary to respond to reviewers of manuscripts we publish. We will be sharing data with the CareEvolution team. The purpose of the data and data sharing will only be for the purpose of verifying the capability to perform data sharing and the data will not be used to any capacity beyond verifying that data was transferred. Security measures regarding sharing have been vetted and approved of by Brian Coleman with the Information Security and Compliance officer at UMass Medical School.

Audio recordings of interviews with patients, providers and program leaders will be transferred via a UMMS IT secure file transfer solution called MoveIT. MoveIT allows users to securely exchange data with business partners inside and outside of our organization. Once a MoveIT account ID is created for both parties (the sender and recipient), files up to 20 GB can be securely shared. These files are encrypted throughout the transfer process and are available for download for up to 10 days. The transcriptionist will receive an account and access from the PIs request through the UMMS HelpDesk. Further details of this feature can be found here https://www.umassmed.edu/it/security/secure-data-transfer-guidance/.

Lastly, analyses of the data will be performed using limited datasets and only aggregate data will be reported. All data will be used for research purposes only; published data will not contain any individual identifiers and will be reported in the aggregate. We will maintain confidentiality of participants throughout the study and maintain this security measure even after the study is completed.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects*

The purpose of this study involves no more than minimal risk to participants. However, we take great care in protecting participant information. All data will be abstracted into secure databases and will be held on secure servers that only study personnel will have access to. Any printed documents will be kept in a locked cabinet.

15. Withdrawal of Subjects Without Their Consent*

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Subjects may be removed from the study if they are no longer an appropriate fit for the study or if the study is cancelled by the University of Massachusetts Medical School Institutional Review Board."

16. Risks to Subjects*

Potential Loss of Confidentiality

Although this is a low risk study, there are still potential risks associated with data collection and information management. The main risk is the potential loss of data confidentiality. However, our study team believes this is unlikely to happen given the protective measures we take.

Protection Against Risks

Minimizing Risks: Our study staff take great efforts to minimize risks associated with this study. More specifically, the data that is collected, whether in the form of paper surveys or online surveys, will be stored in locked cabinets or on secure servers in the office of the research team. Participation in the study will be kept strictly confidential and participant IDs will be assigned to protect their information. Participant data will be de-identified for data exports from CareEvolution. Data entered into the study database will be stored on a secure server using a study participant identification code that does not identify patients or healthcare providers by name. Only the investigators and research staff will have access to study information. All standards mandated by HIPAA for research will be met by implementing comprehensive security policies that meet HIPAA and HITECH standards. This overall provides a framework to securely manage data.

17. Potential Direct Benefits to Subjects*

Participants may directly benefit from the self-monitoring tools a Fitbit provides, such as for increasing physical activity. Results of the study may help providers/clinic staff better deliver these services to cancer patients and survivors in the future.

18. Vulnerable Populations*

UMMS Employees

It is possible for UMMS employees to be included in this study. They could potentially be recruited using the outlined study recruitment methods, and will not be approached directly in person to ensure that no coercion or influence has been exerted. Additionally, employees who agree to participate will be assigned study IDs by the research staff. Data transmitted will be de-identified to ensure participant confidentiality when answering survey questions in the app. Participation in the study is voluntary, confidential, and will not affect their status as a UMMHC employee. We will emphasize these points when communicating with clinic leadership, particularly in the Aim 3 interviews.

Children

Children will not be included in this study.

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Prisoners
Prisoners will not be included in the study.

Adults Unable to Consent
Adults unable to consent will not be included in the study.

Pregnant Women
Pregnant women will be included in the study population.

19. Multi-Site Research*
N/A, this is not a multi-site research study.

20. Community-Based Participatory Research*
N/A

21. Sharing of Research Results with Subjects*
Results will not be shared directly with the participants. All results shared in published research will be in aggregate or summary format and will not include identifiable information about participants. Study results may also be shared with the CareEvolution team to ensure correct data transfer and for improvements to be made for future studies. Additionally, findings may be shared with interested research collaborators to aid in the standardization of a mobile health research protocol.

22. Setting
This study will take place at UMass Medical School. Review and analysis will be conducted in the study staff offices on secure computers at the medical school.

23. Resources Available
All study personnel will read the study protocol, receive appropriate supervision, and possess the appropriate experience (both higher education and related work experience) needed to fulfill their roles and complete their responsibilities for this study. All investigators and project staff are required to receive a Human Subjects Training Certificate. Study staff will also be prepared to dedicate adequate time to fulfill their responsibilities in the study and will meet periodically to ensure that they are informed about the study protocol, the research procedures, their duties, and functions. The Principal Investigator will oversee all personnel and all research activities conducted within this study.

The Principal Investigator (PI) will also have the responsibility of conducting the project at the study site. The PI will have primary oversight of all study personnel and will participate in the design and the execution of the respective study analyses and will be responsible for the reporting of study results. They will also participate in recruitment and informed consent procedures.

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The Programmer/Analyst will perform a range of programming and data management activities essential to conduct the project. They will also assist in the development of study databases, data cleaning and validation activities, algorithms based on study data, and the performance of analyses under the direction of the investigators.

The Project Director/Research Assistant will assist the Principal Investigator in implementing all aspects of the project. They will be responsible for day-to-day oversight of the project, including: developing timelines, work allocation, workflow plans, monitoring project progress and task completion, monitoring spending and effort allocation, and managing correspondence and administrative tasks. They will also monitor ethics and regulatory approvals such as the IRB. They will attend and plan for all project-related meetings as needed. They will also work under the direction of the PI to assist with all study activities, preparing IRB submissions and reports, and developing study materials such as the data collection instruments and intervention-related tools. initial set up of recruitment. They will be responsible for coordinating all meetings related to the study, recording meeting minutes, and sending agendas and reminders prior to each meeting. They will participate in recruitment and informed consent procedures. Lastly, they will be responsible for maintaining communications with all parties participating in the project.

24. Local Recruitment Methods

Potential study participants for Aims 1 and 2 will be recruited from multiple sources, including existing relationships with clinical and community partners. These partners will be given an email (See Survivor mHealth Pilot Recruitment Email.docx) and a flyer (See Survivor mHealth Flyer.docx) to distribute our study's information. We aim to oversample racial/ethnically diverse and socioeconomically disadvantaged participants. Some of our community partners serve both populations and include:

1) LIVESTRONG at the YMCA program leaders: We have worked with local LIVESTRONG at the YMCA programs, which provide free of cost physical activity programs for survivors.
2) YWCA of Central MA program leaders. We have worked with the YWCA of Central MA, who offer programs specifically for Women of Color (WOC) who have cancer diagnoses.
3) UMass Medical Cancer Center providers: We have worked with nurse navigators and advanced practice providers in the 3 UMass Medical Cancer Clinics (UMass Medical, Marlborough and Health-Alliance).
4) The Cancer Collaborative Working Group: This group includes members from the community, including hospitals, local organizations (e.g. YWCA) and other healthcare clinics aimed at increasing the resources for cancer survivors local to the Worcester area. This includes socioeconomically disadvantaged populations.

We will also directly recruit participants who have participated in our past trials and agreed to participate in future research studies with us. This includes three UMMS IRB-approved studies, including two of which the PI (Jamie Faro) was the PI on and working directly with cancer survivors. We will also draw on Dr. David McManus' prior wearable device study participants who were willing to be contacted to participate in future trials and indicated they had a cancer

diagnosis. To recruit these participants, a research assistant from the study staff will send a secure email (See Survivor mHealth Recruitment Email.docx) with the study flyer attached (See Survivor mHealth Flyer.docx) inquiring about their interest in participating. We also request a HIPAA waiver to (*Survivor mHealth HIPAA Waiver*) so we can identify eligible participants in the electronic health record to participate in the study. We will request the minimal information needed in order to identify eligible participants. We will send a letter (*Survivor mhealth Recruitment Letter*) via postal mail to these patients to let them know we will be reaching out to them within 2 weeks, but provide an option to "opt out" by calling, texting, or emailing study staff before the 2 weeks. We are requesting this option to increase our potential pool of eligible participants, as our previously outlined recruitment methods have yielded no enrolled participants to date.

To avoid any type of coercion, we will inform them that their participation is completely voluntary and that it will have no impact on their medical care at UMass. In the inquiry email, we will provide a secure REDCap link to the electronic screening and consent form. We will provide our study number as well so that if the participant has any questions, they may call us before deciding whether or not they would like to participate. They can also do the screener over the phone (See *Survivor mHealth Participant Screener*) with study staff if they wish to do so. If a participant requires medical clearance from a provider based on their responses in the PAR-Q, we will ask participants if they want us to contact the provider with the medical clearance form, or send the form to the potential participant to pass on to their provider (see Survivor mhealth_med_clearance). If participants want us to contact their provider, we will document their permission in REDCap and their providers contact information. Providers will then have the ability to approve or decline the patient's participant in the study and sign the form. We will send providers the medical clearance form either via emailing a secure REDCap link, or via fax as needed to our study's fax line (see Survivor mhealth_med_clearance). We are keeping both options open, as some clinics prefer to fax their medical clearances and want to accommodate their preferences. Study staff will populate the medical clearance form with patient and provider information prior to sending the form to providers.

If they do decide to participate, we will enroll them in the study and provide them with a Fitbit and instructions on how to download the study applications into their smartphone. The RA will then contact the participant for their desired way of delivery of their devices whether that be in person or through the mail.

For Aim 3, we will recruit up to 15 participants, including: Cancer Clinic of the Ambulatory Care Center at the University of Massachusetts Memorial Hospital (UMMHC Clinic) patient navigators, advanced practice providers and oncologists/radiologists. Clinic staff will be recruited from our already existing relationships at the clinic. The Advanced Practice Provider charged with leading the Survivorship Task Committee will distribute an email describing the study to other Navigators in the Breast and Hemonc Clinics (see Survivor mHealth A3 Recruitment Email.docx). Providers will be recruited through existing clinical relationships, by also sending emails to providers and/or having our colleagues in the clinic distribute IRB-approved emails on the PIs behalf. Those interested in participating will contact the PI.

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Compensation: All participants who take part in the study will receive a Fitbit to keep at the conclusion of the trial. Participants who complete the 12-week follow-up measures will receive a $25 gift card within 2 weeks of completion. For those participants who wish to take part in the follow-up 30-minute interview and provider/clinic staff interviews, we will provide them with a $25 gift card within 2 weeks of their completed interview.

25. Local Number of Subjects

We would like the IRB to approve the recruitment of up to 50 participants total. Within this 50, we request approval for 35 participants in Aim 1 to allow for attrition and loss to follow-up, in order to achieve our goal number of 25-30 study participants completing the study. The same participants will be included in Aim 2 interviews. We then request for approval for up to 15 participants in Aim 3 for provider/clinic staff interviews.

26. Confidentiality

We aim to protect participant data and personal information by using de-identified participant ID numbers in place of participants' names. Participant data will be de-identified. This is to maintain participant confidentiality when entering survey responses and Fitbit data. Data that is collected will be accessible only to the research study staff. All data will be kept in secure databases that are password protected and to which only study personnel have access. The databases that will be used during the study are: REDCap and CareEvolution. CareEvolution will have access to the information that is input into the apps, including the answers to the survey and Fitbit data. Fitbit will also have access to the Fitbit data (i.e. step count, heart rate, sleep and calorie data). Again, to protect participants information, we will assign participants a study ID so that data will be de-identified when data transfers occur. The secure database REDCap will be the only place that will have the linkage between the participants de-identifier and name. All data collected from participants will be destroyed 10 years after the final completion of the study. It is also important to note that data uploaded in CareEvolution will be securely stored on servers in the United States or by third party service providers that CareEvolution works with to store and secure information in the United States.

27. Provisions to Protect the Privacy Interests of Subjects

All participants will be told that their participation is voluntary and that they are free to not respond or to terminate involvement at any time with no adverse consequences.

Study subject ID numbers will be used and only the researchers will know the names of the subjects. We will assign each participant a study ID so that data may be de-identified for exports. If a participant does not want to use their email address when signing up for the Fitbit and MyDataHelps app, a research assistant will assign the participant a de-identified study email instead. All information obtained during the study will be considered confidential and will remain on secure servers and locked file cabinets.

To make participants feel at ease, all interviews will be conducted in private phone calls and/or video conference calls (Zoom), which will be password protected. The interviewer for the

phone/web-based video calls will be conducted in an enclosed private room with no other individuals present. We will only collect information needed to conduct the research. Participants will be told that they can skip any questions they want throughout the interview.

The contact information of the Principal Investigator will be given to all participants who participate in this study. Participants will also be asked if they are feeling uncomfortable during data acquisition, and if at any time the participant feels uncomfortable, he or she can choose to stop.

Protection for Risks Associated with Participating in Research Interviews
The study staff will inform all participants that their participation is voluntary, that they are free to not respond, or to terminate involvement at any time with no adverse consequences.

28. Compensation for Research-Related Injury
None; there are no resources available. We do not anticipate any research-related injuries. We believe the research poses no more than minimal risk to subjects.

29. Economic Burden to Subjects
The study apps can be used free of charge when a participant's phone is connected to Wi-Fi. Participants are responsible for any costs from their service provider related to talk/text/data usage if they choose to use the study application while disconnected from Wi-Fi.

30. Consent Process
All research personnel will read and be familiar with HRP-802: INVESTIGATOR GUIDANCE: Informed Consent. A consent form will be sent via a secure REDCap link to eligible individuals. Participants will also have the opportunity to ask any questions they may have before singing the consent form if they wish to participate. If they are interested in participating, they will provide their electronic signature. The study staff will retain their signed form and will store it on the secure REDCap database. For potential participants who do not have internet access and are unable to complete the online consent, we will ask if they would like a paper consent form mailed to their home address. Once they receive the consent form, we will ask them to call us back or we will call them back one to two weeks after mailing the form to review the consent with a study staff member. All questions will be answered, and the staff member will ask if they agree to participate in the study. If yes, this verbal consent will be documented by research staff in REDCap. Printed versions of the signed consent forms will be store it in a locked cabinet or locked file room that will only be accessible to research staff. Once the consent form is signed, we will assign a unique study ID to the participant. For Aim 3, we request to use Fact Sheet to obtain verbal consent to conduct interviews with providers and clinic staff (See Survivor mHealth A3 Fact Sheet.docx).

Waiver or Alteration of the Consent Process: We are requesting a waiver of written consent due the minimal risk of the study. This study involves no procedures that require written consent outside of the research context.

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31. Process to Document Consent in Writing

All research personnel will read and be familiar with HRP-803: Documentation of Informed Consent. The signed consent forms will be printed and kept in a locked cabinet or locked file room that will only be accessible to research staff. Signed consent forms will be retained for a minimum of 5 years after completion of the study.

We are seeking a waiver of written documentation of consent only for the subjects cited in #30 who do not return a signed paper consent, but who do undergo a verbal consent process that is documented by the research staff in REDCap.

32. Drugs or Devices

The study will deploy a Fitbit device to all participants to track progress of their physical activity. The Fitbit will collect data on participants' daily steps, heart rate, and sleep patterns. Please note that this software does not qualify as a medical device according to FDA guidance "Policy for Device Software Functions and Mobile Medical Applications", as it falls into the category listed in Appendix A, #17.