Stepping Into Survivorship: Harnessing Behavioral Economics to Improve Quality of Life in Ovarian Cancer

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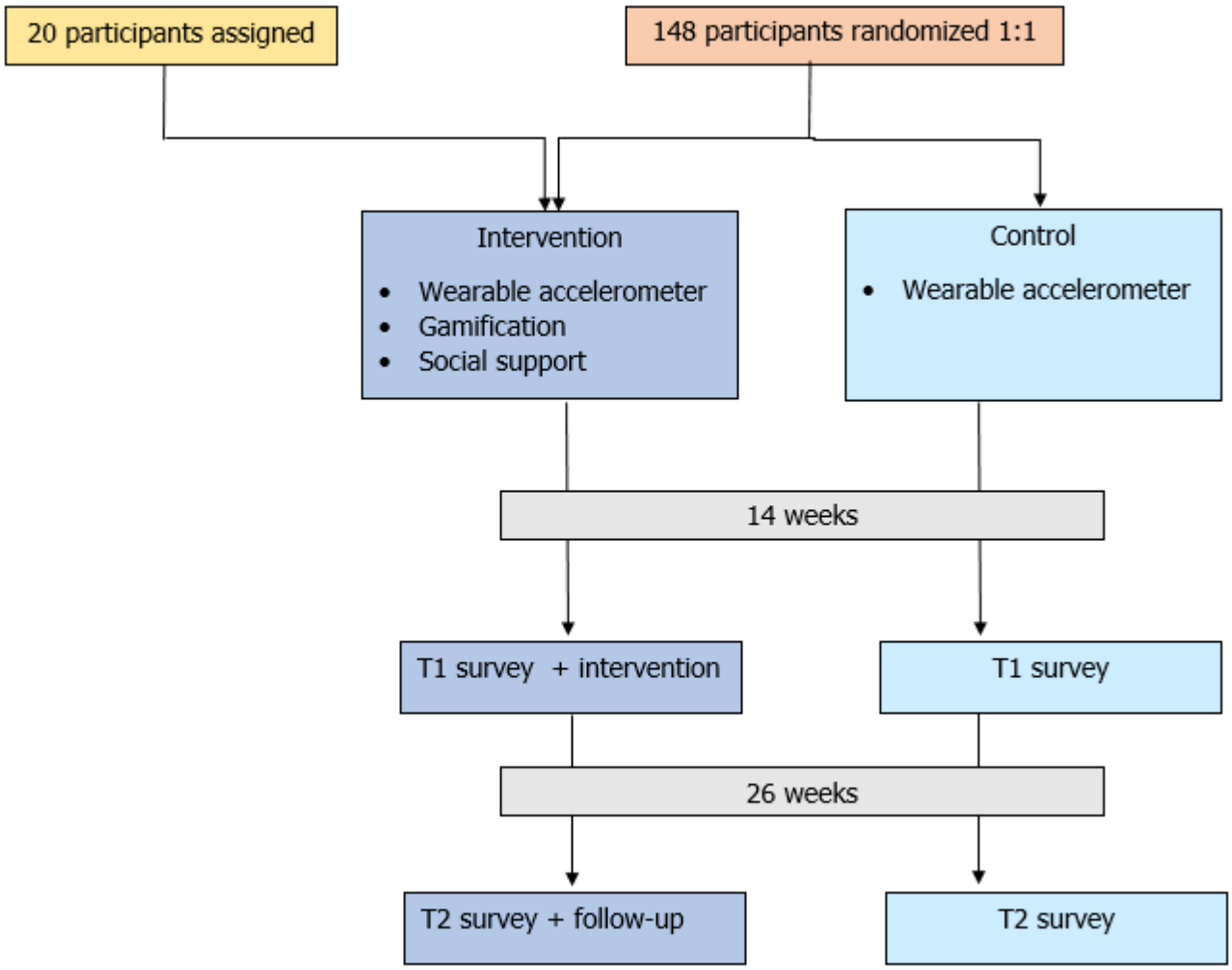
Section 1: Protocol Schema



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1.0 BACKGROUND AND RATIONALE

The transition from active treatment to survivorship is one of the most challenging periods for ovarian cancer survivors.[1] After completing intensive surgery and chemotherapy, survivors often transition to a surveillance period without further treatment and limited contact with their oncology team. Many survivors struggle to reintegrate into their "normal" lives, and experience high rates of physical and emotional distress, fatigue, anxiety, and unmet needs due to disease- and treatment-related sequelae.[2,3]

Exercise has been shown to improve quality of life (QOL), fatigue, and mood, while reducing the risk of disease recurrence and cancer-related mortality in several cancers.[4-7] In ovarian cancer, observational studies have documented associations between exercise and improved QOL,[8-10] but studies have been limited by a reliance upon participants' retrospective recall of activity levels and an inability to examine causality. Only 20% of survivors meet national guidelines for recommended levels of physical activity and 40% report a drop in exercise in the year after diagnosis.[11] Ovarian cancer survivors report an interest in participating in home-based, walking programs to increase physical activity.[12] To date, however, few randomized trials have tested exercise interventions in ovarian cancer.[11] We recently completed a pilot study of wearable accelerometers in ovarian cancer patients at Dana-Farber Cancer Institute (DFCI). Although increasing physical activity was not a primary endpoint, participants were enthusiastic about using wearable devices and spontaneously increased their step counts over a 3-week period (3520 vs. 4374). These finding suggest that smartphone-based interventions coupled with wearable devices may offer a low-cost, scalable strategy to increase physical activity in patients with ovarian cancer.

Smartphone-based health interventions have demonstrated efficacy in achieving sustained behavior change in contexts ranging from smoking cessation to physical activity,[13-17] particularly when combined with insights from behavioral economics. Recently, Patel et al. (co-I) randomized healthy participants to a control group or a mobile health intervention that combined gamification (e.g., the use of non-financial micro-incentives like points, levels, and badges)[18,19] and social incentives (e.g., collaboration, accountability, and peer support) to increase physical activity. During the 3-month study, participants in the intervention arm achieved physical activity goals at significantly greater rates (53% vs. 32%; P<0.001) compared with controls, and averaged nearly 1000 steps more per day (P<0.001).[20] Differences persisted during the 3-month follow-up period after the intervention ended (44% vs. 33%; P<0.001), suggesting that the behavior change may have been sustained through the strengthening of existing social networks. It is unclear whether this strategy can be successfully applied in less healthy populations, including cancer patients, to increase physical activity.

We propose a study to evaluate the efficacy of a social support-based gamification intervention vs. control to increase physical activity in ovarian cancer survivors. Prior to launching a full-scale RCT, we propose a 20-ovarian cancer survivor + partner run-in phase of the social support-based gamification intervention to ensure the interventions' feasibility, acceptability, and preliminary effectiveness. Participants in the social support-based gamification intervention will choose a partner (family/friend) with whom to set collaborative physical activity goals and receive automated feedback through an NIH-funded software platform called Way to Health.[21] All participants, including partners, will use wearable devices to passively collect physical activity data. After completion of the 20 patient + partner run-in phase, we will test the the efficacy of the social support-based gamification intervention vs. control in 148 ovarian cancer survivors' daily steps (primary outcome) and QOL, anxiety, and health care utilization (secondary outcomes) at baseline, 14 and 26 weeks.

2.0 OBJECTIVES

Preliminary Analysis (20 ovarian cancer survivors + partners run-in)

Objective: To assess the feasibility and acceptability of a gamification intervention designed to leverage social incentives and a wearable accelerometer in 20 survivors + partners.

- Hypotheses: It will be feasible to recruit and retain participants and to deliver the intervention.
- Hypothesis: Participants will perceive the intervention as acceptable, and effective in increasing their activity levels.

Final Analysis (RCT with 148 ovarian cancer survivors and 74 partners)

Objective: To evaluate the effectiveness of a modified game-based intervention designed to enhance social incentives in increasing physical activity relative to control.

- Hypothesis: The game-based intervention will increase physical activity at 14 weeks compared with a wearable device.
- Hypothesis: The relative differences in activity between groups will persist at 26 weeks.

Objective: To evaluate the effectiveness of a game-based intervention designed to enhance social incentives in improving ovarian cancer survivors' quality of life and mental health relative to control.

- Hypothesis: Participants in the game-based intervention arm will report significantly better quality of life and lower rates of anxiety or depression at 14 and 26 weeks, compared to those with a wearable device.

A preliminary analysis will be conducted after the 20-patient run-in of the intervention. The final analysis will take place after all patients have completed the study. The final analysis will exclude patients from the run-in phase, since this group of patients will not undergo randomization.

3.0 RESEARCH SUBJECT SELECTION

3.1 Eligibility Criteria

Patients will be eligible if they have newly diagnosed ovarian cancer and are ≤3 months of completing chemotherapy, read English, and do not have cognitive or visual impairments that would preclude participation.

3.2 Exclusion Criteria

Patients will be excluded if they are already participating in an mHealth intervention, are unable to ambulate, do not have a smartphone to transmit data from the wearable tracker, or are unable to select a partner with a smartphone to transmit data from the wearable tracker.

4.0 RESEARCH SUBJECT ENTRY

4.1 Subject Recruitment and Enrollment

4.11 Screening & Recruitment

Prior to obtaining informed consent, study staff will review the electronic medical records of patients who may meet eligibility criteria. These patients' medical records will only be reviewed to confirm this protected health information (PHI), and it will only be shared with providers in the context of patients' eligibility for the study.

When an eligible patient is identified, study staff will contact the patient's oncology provider to confirm she meets the eligibility criteria and to request permission to approach the patient to introduce the study. If the oncology provider deems the patient ineligible or too distressed to participate in a clinical study at this time, the patient will not be approached for inclusion.

PHI will not be shared with anyone outside of the study team and patients' oncology providers. All emails will be sent within the Partners firewall; emails containing PHI that are sent outside the Partners firewall will be sent via the HIPAA-compliant "send secure." A HIPAA waiver requesting permission to review the PHI of these select, potentially eligible patients prior to consent during screening and recruitment has been submitted to justify this process.

If the patient is approved to approach for enrollment, the research assistant (RA) will coordinate with the oncology provider to meet with the patient to discuss the study at the time of her clinic visit.

4.12 Informed Consent

If a patient agrees to learn more about the study, the RA will describe the study, review the consent form, answer any questions, and provide her contact information. The RA will encourage patients to take their time in deciding whether they want to participate in the study or not.

If a patient is interested in participating, the RA will obtain informed consent within the Way to Health platform, as in several other IRB-approved studies throughout the United States (e.g. University of Pennsylvania, Framingham Cohort), in order to ensure that they are properly informed about the data being collected from the accelerometers and by the platform. The partners of patients will also provide in-app consent via Way to Health. The text of the in-app informed consent is included as the single informed consent form for this study.

If a patient is unsure if she would like to participate in the study, they will be offered the consent form to review and the contact information of study staff. If no contact is made after a few days, the RA will contact the patient. If the patient decides to participate, the patient will enter the informed consent process along with a partner of their choosing. If a patient is not interested, the RA will thank her for considering, reassure the patient that the process will have no impact on her care. No further interactions will occur with patients who either decline or prove ineligible for the study. Patients will not be contacted after three unreturned voicemails.

4.2 Subject Registration and Randomization

A member of the study team will register eligible patients enrolled at Dana-Farber in the Clinical Trials Management System (CTMS) OnCore. In order to minimize workflow disruptions for this social/behavioral protocol because the intervention will typically begin immediately after informed consent, registrations will occur retrospectively (as per DF/HCC SOP REGIST-101a) within 10 days of study enrollment if possible. An

investigator will confirm eligibility criteria and a member of the study team will complete the protocol-specific eligibility checklist.

As in the other supportive care interventional trial currently underway in our research group (DF/HCC Protocol 16-477), the study team will register and randomize applicable patients, rather than ODQ doing so, because the intervention will typically begin immediately after informed consent. Randomization will be performed using a 1:1 ratio using a computer-generated random allocation sequence with blocks of 4 in order to maintain balance between study arms over time. Please refer to the protocol schema for details.

5.0 STUDY DESIGN AND METHODS

5.1 Design/Study Type

We will enroll twenty ovarian cancer survivors and their partners (i.e. family member or friend) in a single-arm run-in of the accelerometer + gamification + social support intervention. Next, 148 consecutive patients who meet inclusion criteria will be randomized to one of two arms: accelerometer only (arm 1), or accelerometer + gamification + social support (arm 2).

After the first twenty patients complete the intervention, we will conduct a preliminary analysis (n=20) to assess our aims of feasibility, acceptability, and perceived effectiveness.

After all patients complete the study requirements, we will assess effectiveness outcomes of physical activity, quality of life and mental health for patients randomized to the control arm and intervention arm of the study (n=148). We will exclude patients from the run-in phase from the final analysis since these patients will not undergo randomization. Our final analyses will provide preliminary estimates of feasibility, acceptability, safety outcomes, scale scores, missing data, and participant and physician feedback.

5.2 Selection of Instruments

5.21 Interviews and Surveys

The following measures will be used in the study interviews and surveys, including the *Participant Baseline Interview* (Appendix B) and *Participant Post-Baseline Interview* (Appendix C).

5.21a Global Health Status: EQ-5D-5L

The EQ-5D is a standardized measurement of health status that has been used in a wide range of health conditions and treatments, including cancer patient populations.[22] The EQ-5D-5L is the most recent 5-level version that has proven validity and reliability in a range of patient groups with chronic diseases[23] and cancer.[24] It is a 5-item questionnaire (measuring mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels of perceived problems: 1) no problems, 2) slight problems, 3) moderate problems 4) severe problems, and 5) extreme problems. Patients check the statement level that best describes their current health status in each dimension, which are then scored to generate a patient's unique health state. In the EQ-VAS, patients report a single index value of how good or bad their current health state is on a visual scale that ranges from worst imaginable at zero to best imaginable at one hundred. The EQ-5D-5L can be administered with little to no guidance and takes only a few minutes to complete. Upon scoring, the EQ-5D produces a composite score between 0-1 (multiplied by 100 to generate a number between 0-100), which

represents general health status, normalized for the US population.[25] Lower scores represent worse quality of life, and a change of ≥6 is clinically significant in US cancer populations.[26]

5.21b. Patient and Caregiver Anxiety and Depressive symptoms (HADS)

The Hospital Anxiety and Depression Scale (HADS) is a 14-item scale,[27] measuring symptoms of anxiety and depression, which has been validated for screening for emotional distress in cancer patients.[28] A score of ≥8 indicates significant symptoms of anxiety or depression with good sensitivity and specificity.[29]

5.21c Performance Status: ECOG PS

The Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) assessment is a standard measurement that oncologists often use to assess a patient's current functional level and eligibility for clinical trials. The scale ranges from 0 to 5 and the criteria for each grade is as follows: 0 = Fully active, able to carry on all pre-disease performance without restriction; 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work; 2 = Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours; 3 = Capable of only limited self-care; confined to bed or chair more than 50% of waking hours; 4 = Completely disabled; cannot carry on any self-care; totally confined to bed or chair; 5 = Dead.[30]

The ECOG PS will allow clinicians and participants to provide a standard evaluation of the participant's performance status over time and with minimal burden. Participants will use the patient self-report version that has been used successfully in a study with cancer patients.[31] We expect that it will take 1-2 minutes to answer the question.

5.21d Literacy Measures: Health Literacy and Numeracy

Health literacy[32] and numeracy will be collected for all participants at baseline. We estimate that it will take participants approximately 5 minutes to complete all of the literacy measures.

5.21e Demographic Information

Basic demographic information will be collected for all participants, including: age, marital status, race/ethnicity, education, household structure, income, and employment. The questions will only take a few minutes to complete.

5.21f Self-reported Health Care Utilization

Patients will be asked to self-report visits to their primary care doctors, oncologists, and other specialists during the time in which they are participating in the study using a validated medical event form (Appendix D). In addition, they will self-report laboratory tests, radiographic imaging, emergency department visits, hospitalizations, and length of visit.

5.21g PROMIS 29

Health-related quality of life will be assessed using the PROMIS-29, a non-disease-specific measure.[33] The PROMIS 29 is composed of eight subscales. Participants will complete the physical function, fatigue, sleep disturbance, social roles/activites, pain interference, and pain intensity subscales. In order to reduce survey burden on participants, the subscales on anxiety and depression will be omitted, since these constructs are captured in the Hospital Anxiety and Depression Scale.

5.21h Social Support Survey

The Social Support Survey instrument is a brief, multi-dimensional measure developed for patients in the Medical Outcomes Study, a two-year survey developed for patients with chronic conditions.[34] The survey consists of four functional support scales (emotional/informational, tangible, affectionate, and positive social interaction); a composite, overall functional social support index can be calculated from the subscale items. Each subscale is reliable (Cronbach's alpha > 0.91) and stable over time.[34]

5.21i Brief COPE

The Brief COPE is a 28-item measure developed to assess a broad range of coping responses.[35] The Brief COPE has been validated in several populations including breast cancer patients and community samples.[35] Subscales of the Brief COPE include use of emotional support, religion, and self-distraction, and individual subscales can be used independently. The Brief COPE will be administered to patients during the participant baseline interview.

5.21j Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity Questionnaire (FACT/GOG-NTx)

The Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity (FACT/GOG-Ntx) questionnaire assesses concerns associated with chemotherapy-induced neuropathy, and evaluates the impact of neuropathy on health-related quality of life.[36] The FACT/GOG-Ntx has been shown to be reliable and valid, and has been used in gynecologic and ovarian cancer patients.[36,37] FACT/GOG-Ntx is included in the Functional Asessment of Chronic Illness Therapy (FACIT) Measurement System, a collection of health-related quality-of-life measures targeted to chronically ill patients.

5.21k NCCN FACT Ovarian Symptom Index-18 (NFOSI-18)

Symptom burden will be assessed using the NFOSI-18, a clinically-meaningful, ovarian cancer-specific index reflecting the symptoms rated as highest priority by clinical experts and women with ovarian cancer.[38] The NFOSI-18 has high content validity[39] and is reliable.[40]

5.21l Herth Hope Index

We will assess patients' and caregivers' hope using the Herth Hope Index, an abbreviated instrument used to assess hope in adults in clinical settings.[41] The HHI is a twelve-item scale scored on an ordinal Likert-format scale from 1 to 4, where a score of 1 indicates "strongly disagree" and a score of 4 indicates "strongly agree." The HHI is both reliable (alpha coefficient = 0.97) and valid.[42] The HHI will be used during the baseline and post-baseline interviews.

5.21m Cancer Impact on Finances and Employment

The impact of cancer on patients' finances and employment will be assessed with three questions adapted from the Individualized Cancer Care study, which examined women's breast cancer treatment experiences and decision making.[43] Patients will be asked if they worked for pay during any of their treatment for ovarian cancer, how many days of work they have missed because of their cancer or cancer treatment, and about the financial impact of having cancer.

5.21n Assessment of Survivor Concerns

The Assessment of Survivor Concerns is a five-item questionnaire which measures fears about recurrence and health in cancer survivors.[44] The ASC has high internal consistency and validity, and is appropriate in both short-term and long-term survivor populations.

5.21o Perceived Stress Scale

The Perceived Stress Scale is a measure of the degree to which situations in an individual's life are appraised as stressful.[45] The Perceived Stress Scale has previously been used to assess global stress in cancer patient populations.[46] A 4-item version of the scale will be used, in order to limit survey burden on participants.

5.21p Cancer Self-Efficacy

Self-efficacy will be assessed by adapting items from the breast cancer self-efficacy scale (BCSC), a 12-item measure with high reliability (Cronbach's alpha = 0.89) and excellent content and construct validity.[47] The BCSES assesses self-efficacy specifically in the context of cancer survivorship. Individual items will be modified to reflect ovarian cancer survivorship.

5.21q Social Support and Exercise Survey

The Social Support and Exercise Survey[48] measures perceived social support specific to health-related exercise behaviors. The measure specifically assesses the level of support individuals making health behavior changes, such as those suggested in this intervention (i.e exercise), felt they were receiving from family and friends.[48] Separate assessment categories for "family" and "friends" will be combined into a single "family/friends" column in order to account for variation in participants' exercise partners.

5.21r Physical Activity Vital Sign

The physical activity vital sign (PAVS) is a clinical tool designed to screen for physical activity in adults, which gauges adult moderate to vigorous physical activity levels.[49] The PAVS consists of two questions: one asking how many days per week the subject engages in moderate to strenuous exercise, and the other asking for the number of minutes exercised each day. The product of these two numbers is used to calculate the total minutes per week of physical activity.

5.22 Medical Chart Abstractions

5.22a Health/Treatment Information

Patients' medical charts will be reviewed to abstract health and treatment related information, including disease site, comorbid health conditions, number of prior chemotherapy regimens, and time since diagnosis.

5.22b Call Log

Per usual care, program nurses in the Division of Gynecologic Oncology will document participants' phone calls with clinical staff in participants' electronic medical health records. Study staff will abstract information about these phone calls during a participant's enrollment. Data collected for each call will

include: date/time, incoming/outgoing, left message, reason for the call, symptoms documented, and the outcome.

5.23 Six-Minute Walk Test

The six-minute walk test[50] is a measure of functional capacity which measures the distance that a atient can quicky walk on a flat, hard surface in a period of six minutes. The self-paced six-minute walk test assesses the sub-maximal level of functional capacity.[51] Because patients choose their own intensity of exercise, the six-minute walk test is a good proxy of the functional exercise level for daily physical activities since most ADLs are performed at sub-maximal levels of exertion.[51] The six-minute walk test has excellent reliability and validity across a variety of populations, including geriatric and elderly populations.[52] Patients will be asked to complete the six-minute walk test at baseline and post-baseline visits.

5.24 Debriefing Interviews

Upon completion of the study requirements, patients and their partners will be asked to provide feedback on their experience in the intervention through a brief semi-structured interview. An interview guide is provided in Appendix F: Debriefing Interviews; as is typical in semi-structured interviews, we may also explore additional themes that emerge over the course of the study and interviews. Debriefing interviews will be audio-recorded (and transcribed if funds permit). Recordings will be stored on secure, HIPAA-compliant folders and in locked filing cabinets; transcriptions will be performed locally at Dana-Farber or using a HIPAA-compliant transcription vendor. We will also debrief with referring clinicians/co-investigators on how to improve the study procedures.

5.3 Description of Interventions

Participants in both the intervention and control arms of the study will receive a wearable accelerometer and their steps will be monitored passively by the Way to Health platform. In addition, participants in the intervention arm of the study will receive social support and gamification built into the Way to Health platform.

5.31 Monitored Wearable Accelerometer: Fitbit Charge 2

The Fitbit Charge 2 is an accelerometer that is worn on the wrist and tracks users' heart rate continuously in addition to steps, distance, calories, and active minutes. The addition of an optimal heart rate sensor enables monitoring of the time that the tracker is being worn (e.g., adherence).[82, 83] Wrist-worn activity trackershave been shown to accurately measure heart rate when compared with electrocardiography,[84, 85] have good test-retest reliability (intraclass correlations of 0.75-0.95)[81] but over count steps compared with the gold standard ActivPAL in free-living conditions due to the variability in limb-specific activities[86] One of the advantages of the Fitbit Charge 2 is it allows for close monitoring of adherence to the device over time because of its continuous measurement of heart rate. The disadvantages include: it is not as accurate as a hip-worn device,is dependent upon the user to recharge it every 3 days, and may be less accurate if the participant is dependent upon a device for ambulating (e.g., cane or walker) or wears the device on her non-dominant arm.Data from the wearable accelerometer will

be monitored by the Way to Health Platform, and patients may also choose to view their steps though Fitbit app, which accompanies the accelerometers.

5.32 Way to Health Platform

The Way to Health platform is an automated information technology platform developed at the University of Pennsylvania that integrates wireless devices, clinical trial randomization and enrollment processes, messaging (text, e-mail or voice), self-administered surveys, automatic transfers of financial incentives, and secure data capture for research purposes.[21] Way to Health has been used with patients in IRB-approved protocols in prior behavioral intervention studies.[59-61] The Way to Health platform will be used in both the control arm and interventional arm of our studies. In the control arm, patients will receive access to the Way to Health platform in order for the study team to receive their accelerometer data, and to process payments – however, none of the gamification features of the platform will be turned on for patients in the control arm. In the intervention arm, patients and their partners will have access to the Way to Health platform in order for the study team to receive their accelerometer data and to process payments. Patients and their partners in the intervention arm will also have access to the gamification features of the Way to Health platform, as described in section 5.34.

5.33 Control

On Day 0, patients in the control group will receive a wearable accelerometer and the study's research assistant will explain to them how to use the accelerometer. Control group participants will receive one follow-up phone call to resolve technical issues (more if needed) and will be contacted during the study if data is not being properly received or if they are nonadherent. Fitness tracker data will be monitored passively via the Way to Health Platform.

5.34 Intervention

On Day 0, patients receiving the intervention will be given two wearable accelerometers, and the study's research assistant will explain to them how to use the devices. Participants will select a family member or friend to enhance social incentives by motivating the individual towards her goal by participating in the intervention with them,[117] so the patient will be asked to give the second fitness to a partner with whom she will participate in the study. After recording their steps passively for 2 weeks, patients will be asked to set a step goal to increase with their partner. The step goal should be of 33% to 50% higher than baseline or to choose their own goal (minimum ≥1500 steps greater than baseline). Ovarian cancer survivors and their partners will sign a pre-commitment contract agreeing to try their best to achieve their daily step goal, which helps to motivate behavior change.[62,63] Participants will also receive an exercise prescription (Appendix E) which has been recommended in the care of midlife and older women[64] and aims to motivate exercise behavior change.[65]

At the start of each week, participants receive 70 points (10 for each day). Points are endowed to leverage loss aversion – a concept from prospect theory that reveals that individuals are more motivated by losses than gains.[16] Each day participants are informed of their step count. If the step goal was achieved, they keep the points. However, each day the goal is not met, they are informed that they lost 10 points. Points are replenished at the start of the week to leverage the "fresh start effect." Participants will be offered the opportunity to move up or down "levels" within the platform. At the end of the week, if the participant has ≥40 points, she will advance up one level. Levels include: blue (lowest), bronze, silver, gold, platinum (highest). If she has <40 points, she will drop down one level. This creates a sense of achievable goals (goal gradients) and longer-term loss aversion.

5.4 Data Collection

Table 1 specifies the instrument and intervention data collection timeline.

Table 1. Instrument Data Collection

		DAY		
		Visit 0	Visit 14 wks	Visit 26 wks
INSTRUMENT	Participant Baseline Interview	✓		
	Participant Post-Baseline Interview		✓	✓
	Six-Minute Walk Test	✓	✓	✓
	Debriefing Interview			✓
	Platform Data	→	→	→

Data obtained via interviews, surveys and chart abstractions will be stored on the Harvard REDCap server and/or the Way to Health platform.

Accelerometer data will be stored with Way to Health. All Way to Health data is de-identified and stored in mySQL-based systems with appropriate information and environmental security, and de-identified data exports maintain data integrity and assures safeguards. See section 5.55 for a detailed description of Way to Health's data security and privacy measures.

5.5 Description of Study Process

5.51 Instrument Administration

Participant Baseline Interview:

- The RA will administer the survey to patients via a guided interview on Day 0 (Baseline Visit).
- Patients will complete the interview on the same day informed consent is obtained; if this is not possible, the RA and patient will plan to complete it at a subsequent clinic visit or remotely.
- Estimated time to completion: 45 minutes.

Participant Post-Baseline Interview:

- The RA will administer the interview to patients, ideally within +/- 14 days of the projected assessment date (Post-Baseline Visit). The flexible administration window accounts for variations in participants' schedules.
- Estimated time to completion: 30 minutes.

Chart Abstraction:

- An RA will review patients' medical charts to complete the chart abstractions form at the time of participants' baseline and post-baseline visits.
- Chart abstractions will, if possible, be completed within 10 days of participants' study interviews.

5.52 Intervention Administration

5.52a Intervention Administration Overview

The intervention will begin the day that a participant receives an accelerometer and enrolls in the study on the Way to Health platform. See the protocol schema for details.

Control Arm: Participants assigned to the control arm will receive a wearable accelerometer and be enrolled in the Way to Health platform on "day 0." They will be asked to wear the wearable accelerometer daily for 14 weeks. Patients in the control arm will not receive social support or gamification in the Way to Health platform. Research assistants will be in contact with patients to resolve any technical issues they may be having and to address issues of nonadherence. At approximately 14 weeks after study enrollment, patients will be asked to complete an follow-up interview (T1), be moved out of the "active intervention" phase and enter into the follow-up phase. During the follow-up phase, research assistants will be accessible for questions about technical issues. At approximately 26 weeks after study enrollment, patients will complete a second follow-up interview (T2) and their participation in the study will end.

Intervention Arm: Patients assigned to the intervention arm will be enrolled in the Way to Health platform on "day 0." They will receive two wearable accelerometers – one for themselves and one for a loved one – in order to leverage the effects of social support on behavior change. Patients and their loved one will be asked to wear the wearable accelerometer daily for 14 weeks. Participants in the intervention arm will also be asked to sign a pre-commitment contract, receive an exercise prescription, receive "gamification" via the Way to Health platform, and select a step goal with their partner. Research assistants will be in contact with patients to resolve any technical issues they may be having and to address issues of nonadherence. At approximately 14 weeks after study enrollment, patients will be asked to complete an follow-up interview (T1), be moved out of the "active intervention" phase and enter into the follow-up phase. During the follow-up phase, patients and their loved ones will still be able to access the Way to Health platform but the social support and gamification components will be turned off. In follow-up, research assistants will be accessible for questions about technical issues and will monitor adherence via registered steps collected by Way to Health. At approximately 26 weeks after study enrollment, patients will complete a second follow-up interview (T2) and their participation in the study will end.

5.52b Intervention Administration Timeline

Baseline

Instructional Session:

- Study staff will instruct patients (and their partners, if applicable) on how to use the Way to Health Platform and fitness trackers, and assist patients in the initial setup of the new technology.

Baseline Interview:

- Patients will be asked to complete a baseline interview. Every attempt will be made to conduct these interviews in-person. However, if this is not possible, interviews will be conducted over the phone or through email or physical mail, depending on participant preference.

Six-Minute Walk Test:

- Trained study staff will administer the six-minute walk test to ovarian cancer survivors.

Intervention

- *Intervention Arm Only:* After recording their steps passively for 2 weeks, participants will be asked to set a step goal to increase with their partner. The step goal should be of 33% to 50% higher than baseline or to choose their own goal (minimum ≥1500 steps greater than baseline). Study staff will ask patients and partners to fill out a pre-commitment contract agreeing to try their best to achieve their daily step goal, which helps to motivate behavior change. Participants will also be given an exercise prescription.

T1

- Approximately 14 weeks after beginning to use the accelerometers and Way to Health platform, patients will complete a follow-up interview (T1).
- Patients will transition from the "active" phase of the study to the "follow-up phase" of the study.
    - Control arm: During the follow-up phase, research assistants will be accessible for questions about technical issues and will monitor adherence to the activity tracker via registered steps collected by Way to Health.
    - Intervention arm: During the follow-up phase, patients and their partners will still be able to access the Way to Health platform with its social support and gamification components. However, in follow-up, research assistants will be accessible for questions about technical issues and will monitor adherence to the activity tracker via registered steps collected by Way to Health.
- Trained study staff will administer the six-minute walk test to ovarian cancer survivors.

T2

- Approximately 26 weeks after beginning to use the accelerometers and Way to Health platform, patients will complete a follow-up interview (T2).
- Following completion of the T2 interview, patients will be thanked for their study participation and their enrollment in the study will end. Patients and their partners will be allowed to keep their wearable accelerometers.
- Trained study staff will administer the six-minute walk test to ovarian cancer survivors.

5.52c Intervention Administration Additional Concerns

Platform Use and Compliance:

- Participants will be instructed to avoid adjusting the platform settings to ensure data is collected. Participants will be contacted if the accelerometers or data collection via the platform is not working properly, or if there are issues with adherence.
- Participants will have access to a research assistant to help resolve technical issues.

Tracking Devices:

- The accelerometers assigned to each participant will be tracked according to the product serial number and assigned unique ID number.
- Participants will be allowed to keep the accelerometers as a token of appreciation for their participation in the study, and to minimize potential transmission of skin infections (e.g. methicillin-resistant Staphylococcus aureus) between participants.

5.53 Special Concerns

5.53a Lost Accelerometers

If a participant reports to study staff that they lost an accelerometer, study staff will provide a replacement, either in person or via mail, as soon as possible.

5.53b Surveys

Participants will be contacted in advance to complete their upcoming study survey. After three unreturned voicemails, they will not be contacted again for additional surveys.

5.54 Compensation

Ovarian cancer survivors in both arms will receive gift cards valued at $25 at 14-weeks, and $50 at 26-weeks if study requirements are completed, including post-baseline assessments and adherence to the accelerometers.

5.55 Data Security & Privacy

The data security and privacy of study participants is of utmost importance, and we have taken stringent measures to protect our participants' data. The Penn Medicine Academic Computing Services (PMACS), based out of the University of Pennsylvania, will be the hub for the hardware and database infrastructure that will support the project. The PMACS provides a secure computing environment for a large volume of highly sensitive data, including clinical, genetic, socioeconomic, and financial information. Among the IT projects currently managed by PMACS are: (1) the capture and organization of complex, longitudinal clinical data via web and clinical applications portals from cancer patients enrolled in clinical trials; (2) the integration of genetic array databases and clinical data obtained from patients with cardiovascular disease; (3) computational biology and cytometry database management and analyses; (4) economic and health policy research using Medicare claims from over 40 million Medicare beneficiaries.

All data for this project will be stored on the secure/firewalled servers of the PMACS Data Center, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by University of Pennsylvania system managers. Our collaborators at the University of Pennsylvania use highly secure methods of data encryption for all transactions involving participants' financial information using a level of security comparable to what is used in commercial financial transactions. We believe this multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health Systems medical records, greatly minimizes the risk of loss of privacy.

We will take additional steps to minimize the risk of data security breaches by linking individually identifiable health information with participant ID numbers only in a password-protected Excel file that is stored

on Dana-Farber servers, protected by Partners IS infrastructure, and accessible only to members of the study team.

5.6 Adverse Reactions and Their Management

5.61 Reporting Adverse or Unanticipated Events

Potential adverse events (AE) for this project are expected to be all non-medical in nature. There is small risk of physical injury. Participants could experience discomfort while wearing the Fitbit on their wrist. Subjects may experience mild anxiety when answering survey questions about emotional issues or questions about coping challenges or difficulties related to discussing the subject matter. The PI will report unanticipated and serious adverse events to the IRB in a timely manner on an ongoing basis. For the purpose of this study a Serious Adverse Event (SAE) is defined as an event that, as a direct result of the study, causes serious harm to the subject (e.g., hospitalization).

5.62 Anticipated Reactions & Reaction Management

Should participants become exceedingly upset, disoriented or fatigued or need to attend to matters of personal care during the surveys, study staff will ask the subject if they would like to take a break or reschedule the survey for another time. In the event that participants experience distress while completing surveys, we will follow standard procedures used in our behavioral health intervention studies for counseling and referral. The PI will be notified immediately and participants will be provided with the pager numbers for both the study PI and the study psychiatrist included in the consent form. Dr. Ilana Braun, a DFCI psychiatrist, has agreed to serve as a psychiatrist on the study. Dr. Braun will evaluate any participants who are distressed for risk of imminent danger and refer them to appropriate services if they are needed.

6.0 STATISTICAL ANALYSIS

6.1 Primary and Secondary Endpoints

Primary Endpoints

1) *Preliminary Analysis:* To assess the feasibility, acceptability and perceived effectiveness of the accelerometer + social support + gamification intervention in 20 ovarian cancer patients and their partners.
2) *Final Analysis:* To compare the change in daily steps from baseline to the 14-week intervention period between the intervention arm and control arm.

Secondary Endpoints

Preliminary Analysis:

1) Comparing the change in daily steps from baseline to the 14-week and 26-week intervention periods.
2) Comparing the change in quality of life (EuroQol EQ-5D index) and symptoms of anxiety and depression at baseline, 14 and 26 weeks.
3) Comparing additional clinical and quality-of-life outcomes including functional capacity (6-minute walk test), symptom burden (NFOSI-18), fear of recurrence (ASC) and others, at baseline, 14 and 26 weeks.

Final Analysis:

1) Comparing the change in daily steps from baseline to 26 weeks between the intervention arm and control arm.
2) Comparing the change in quality of life (EuroQol EQ-5D index) and symptoms of anxiety or depression (HADS) at 14 and 26 weeks between the intervention arm and control arm.
3) Comparing health care utilization at 14 and 26 weeks between the intervention and control arm.
4) Comparing additional clinical and quality-of-life outcomes including functional capacity (6-minute walk test), symptom burden (NFOSI-18), fear of recurrence (ASC) and others, at 14 and 26 weeks between the intervention and control arm.

6.2 Sample Size and Statistical Power or Precisions

Preliminary Analysis

A convenience sample of 20 ovarian cancer survivors and 20 partners will be enrolled for the run-in portion of the study. Due to the limited sample size, statistical analyisis will be descriptive in nature.

Final Analysis

148 patients will be randomized 1:1 to one of the two arms – accelerometer only, or accelerometer + gamification + social support. For the outcome of change in steps, we will compare the change in daily steps from baseline to the 14-week T1 time point between the intervention arm and control arm to conclude that the intervention is promising for further study. We use 1000 steps as our threshold for powering statistical significance, which for the average person is about half a mile. A priori power calculations assumed a baseline mean step count of 6000 steps in the control group with a standard deviation of 2000 steps, a 15% dropout rate, and a 2-sided α of 0.05. It was estimated that a sample of 148 participants (74 per arm) would ensure 80% power to detect a 1000 step difference between the gamification + social support and control arms in the change in mean daily steps from baseline to the maintenance phase.

Fitness tracker	Gamification / social support	Arm	Sample size
+	-	1 (Accelerometer only)	74
+	+	2 (Accelerometer + gamification + social support)	74
		Total	148

6.3 Analysis Plan

6.3a Preliminary Analysis (20 ovarian cancer survivors and 20 partners)

Feasibility: We will record eligibility, approach, interest, enrollment, interview, follow-up rates, and reasons for non-participation at each stage. We will assess the completeness of the study measures. Definitions of adequate feasibility include: 1) ≥60% enrollment among eligible patients, 2) ≥70% adherence to the wearable accelerometer ≥4 days per week, and 3) ≥70% follow-up rate at 14-weeks among enrolled participants.

Acceptability: Upon completion of the study, participants will be asked to rate two questions: 1) "Participating in this study placed a substantial burden on me" and 2) "I wish I had not agreed to participate in this study." Response options will include: strongly disagree, disagree, agree, and strongly agree. Acceptability will be defined as ≤20% of participants answering agree or strongly agree to either question.

Perceived effectiveness: Perceived effectiveness will be defined as ≥70% of participants indicate that study participation motivated them to increase their activity levels..

Exploratory outcomes: Exploratory outcomes in the preliminary analysis will include change in daily steps from baseline to 14 and 26 weeks, QOL, and mental health.

6.3b Final Analysis (74 patients in each arm)

Change in steps: The primary outcome will be the change in participants' daily step counts from baseline to the end of the 14-week intervention period. A secondary outcome will be the change in participants' daily step counts from baseline to the 26-week follow-up period.

Quality of life: A secondary outcome will be the change in the participants' quality of life from the baseline to 14- and 26-week follow-up periods, as assessed with the NIH-funded Patient Reported Outcome Measure Information System (PROMIS)-29 scale.

Mental health: Another secondary outcome will be the change in the participants' symptoms of anxiety and depression from the baseline to 14- and 26-week follow-up periods, as assessed by the Hospital Anxiety and Depression Scale (HADS).

Additional clinical and QoL outcomes: We will assess changes in additional clinical and quality of life outcomes, including functional capacity (6-minute walk test), symptom burden (NFOSI-18), fear of recurrence (ASC) and others, at 14 and 26 weeks between the intervention and control arm.

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8.0 APPENDICES

Recruitment/Enrollment:

Appendix A: Opt-out card (retired)

Instruments:

Appendix B: Participant Baseline Survey
Appendix C: Participant Post-Baseline Survey
Appendix D: Medical Event Form
Appendix E: Exercise Prescription
Appendix F: Debriefing Interview Guide