HOME-BASED RESISTANCE TRAINING IN ENDOMETRIAL CANCER SURVIVORS

Feasibility and acceptability of a telehealth-based resistance training intervention for endometrial cancer survivors

Principal Investigator:
Lisa Cadmus-Bertram, Ph.D.
University of Wisconsin - Madison

PROTOCOL VERSION and AMENDMENTS

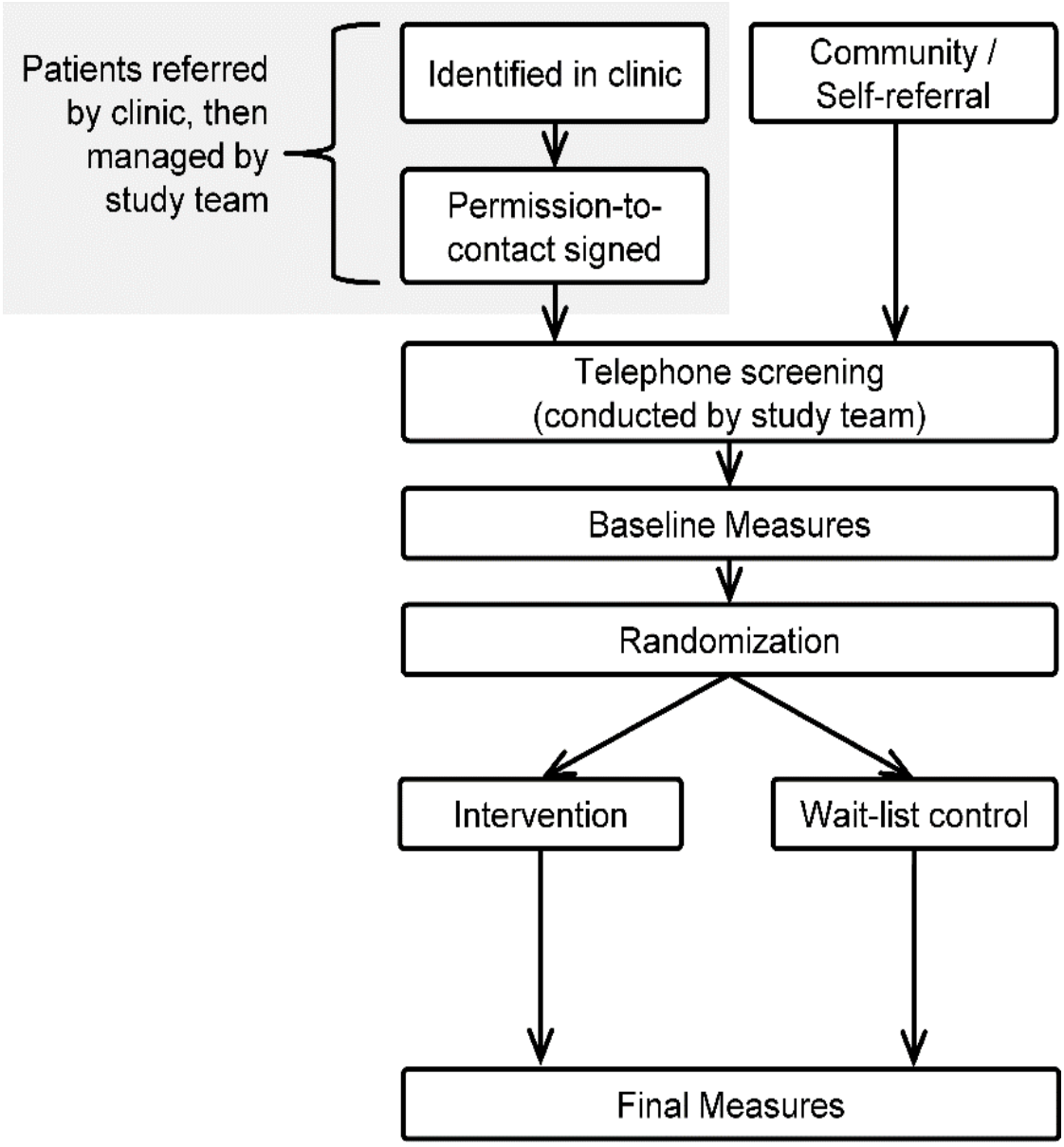
Protocol Version	Date	Change Initiated (Initials)	Brief description of protocol modification/actions requested, if any
Version 1.0	2/5/2018	JSG	Preliminary draft
Version 1.1	2/7/2018	JSG	Updated for review by PRMC at UWCCC
Version 1.2	2/13/2018	JSG	Updated post meeting Ryan Spencer
Version 1.3	3/9/2018	JSG	Updated again for review by PRMC
Version 1.4	4/2/2018	JSG	Updated post-review of PRMC
Version 1.5	4/19/2018	JSG	Update: mental health questions, repeated measures and qualitative measures added
Version 1.6	7/5/2018	JSG	Updated informed consent as separate document
Version 1.7	7/14/2018	JSG	Updated a new, streamlined checklist in the appendix
Version 1.8	08/24/2018	JSG	Revised after IRB pre-review
Version 1.9	08/30/2018	JSG	Revised after second IRB pre-review
Version 1.10	09/26/2018	JSG	Updated post PRMC re-review
Version 1.11	10/04/2018	JSG	Updated after PRMC, QA and Compliance manager review at the UWCCC.
Version 1.12	11/24/2018	JSG	Updated the participant compensation information due to oversight in previous versions.
Version 2.1	3/19/2019	JSG	R03 awarded: updating accrual goals, length of intervention, recruitment strategies

1 Study Summary

Title	Feasibility and acceptability of a telehealth-based resistance training intervention for endometrial cancer survivors
Short Title and Precise	Home-based resistance training in ECS
Protocol Number	UW18013
Methodology	Randomized, two arms including a wait list control
Study Duration	One year
Study Center(s)	UW-Madison
Objectives	Determine adherence rates to prescribed exercises, quantify changes in lean body tissue and blood biomarkers, and functional changes in performance
Number of Subjects	40
Diagnosis	Endometrial cancer
Main Inclusion Criteria	Diagnosis of Type I, stage I-IIIc endometrial cancer, with completion of primary treatment
Main Exclusion Criteria	Absolute contraindications to exercise, failure on pre-MVPA screening
Study Product, Dose, Route, Regimen	Home-based, full-body resistance training exercises of 2-3 sets of 8-10 reps two days a week for 10 weeks, with a five week follow up period
Statistical Methodology	Paired comparisons to assess pre-post differences within groups, as well as between groups pre and post

Schematic of Study Design

Flow diagram or study calendar (e.g., randomized controlled trial)



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2 Key Roles

Following is a list of all personnel in key roles:

Principal Investigator: PI
Lisa Cadmus-Bertram, PhD, Assistant Professor of Kinesiology
University of Wisconsin-Madison
2000 Observatory Drive
Madison, WI 53706
(608) 265-5946
Lisa.bertram@wisc.edu

Co-Investigator / Medical monitor
Ryan Spencer, MD, Assistant Professor
University of Wisconsin-Madison
600 Highland Ave
H4/6, 6188 Clinical Science Center
Madison, WI 53792
(608) 265-1700

Biostatistician
Ron Gangnon, PhD, Professor of Population Health Sciences/Biostatistics
University of Wisconsin-Madison
610 Walnut St
603 Warf Office Building
Madison, WI 53726

Project Coordinator
Jessica Gorzelitz, MS, Research Fellow
University of Wisconsin-Madison
2000 Observatory Drive
Madison, WI 53706
(608) 262-1167
gorzelitz@wisc.edu

Introduction

This document is a protocol for a human research study. This study is to be conducted according to applicable government regulations and Institutional research policies and procedures, and State Law.

2.1 Background and Rationale

Endometrial cancer survivors have an extremely high prevalence of inactivity and obesity. The US has a large and rapidly growing population of 760,000 endometrial cancer survivors, which will increase 55% by 2030.[1, 2] Despite a generally favorable 81% 5-year survival rate, patients remain at increased risk for cardiovascular disease, diabetes, and other cancers.[3] A key risk factor for endometrial cancer is unopposed estrogen, which is linked to inactivity and obesity.[4, 5] Indeed, up to 90% of Type 1 endometrial cancer patients are obese.[6] Inactivity and obesity are associated with poorer outcomes among survivors. In the NIH-AARP Diet and Health Study, endometrial cancer survivors who were physically active had a lower all-cause 5-year mortality rate and lower BMI was associated with lower risk of both overall and disease-specific mortality.[7]

There is a critical need for data about the feasibility and benefits of strength training in this population. Other interventions have demonstrated that walking and aerobic exercise are safe and feasible in endometrial cancer patients.[8-11] However few published studies have examined strength training in endometrial cancer survivors, and these have done so only in combination with aerobic PA intervention (and often also dietary change) in the context of a larger multi-component intervention.[12, 13] Therefore the specific contribution of strength training remains unknown. This is important because aerobic exercise leads to improvements in the cardiovascular system, whereas resistance training has specific effects at the musculoskeletal level in addition to systematic cardiovascular benefits.[14] Strength training increases muscle mass, which is critically important given the high prevalence of sarcopenic obesity among middle- aged and older women.[15] It is also highly effective for functional improvements such as increased strength and balance.[16, 17] Indeed, in other cancer survivor groups, strength training is more effective than aerobic exercise for improving functional status.[14] Another benefit of strength training is that it is a realistic health promotion option given poor long-term efficacy of weight loss interventions.[18] Unfortunately, without intervention, strength training has a relatively high barrier to participation among women, due to factors such as lack of knowledge and difficulty finding time to travel to a gym.[19]

Previous strength training interventions not optimized for rural populations. Rural areas are often underserved in terms of medical access/use and educational and economic opportunities.[20, 21] Consequently, rural populations are diagnosed at later stages of cancer[22] and have higher rates of cancer mortality.[23] Unfortunately, previous strength training research in cancer populations have mainly used supervised sessions with a personal trainer at a gym, an approach that is not feasible in many rural settings.

Overview of proposed research. To address these gaps, we propose a 2-arm pilot trial of a home-based strength training intervention (vs. waitlist control) among 40 endometrial cancer survivors. The intervention will consist of (a) an initial in-person instructional session; (b) instructional materials and resistance training equipment (e.g., resistance bands) and (c) support and feedback provided via video coaching sessions. The purpose of a pilot trial is not to conduct hypothesis testing, but rather to field-test the logistical components of the study to incorporate into a larger, future study design.[24] With small samples, the true effect size is more likely to be under or overestimated, therefore hypothesis testing is not valid.[25] Our aims are designed accordingly.

2.2 Aims and Hypotheses

The proposed trial will determine the feasibility of an at-home resistance training protocol and measurements of exercise logging, functional fitness testing, DXA, dried blood spots and questionnaire measures. Participants will be assigned either to the resistance training program (i.e., initial in-person instructional session, telephone coaching, and self-monitoring) or to a comparison arm (wait-list control).

- **Aim 1:** To determine the feasibility of recruiting and retaining endometrial cancer survivors to a home-based resistance training 2 sessions per week of 20-40 minutes of exercise. *We hypothesize that we will meet the accrual goal and maintain >90% retention.*
- **Aim 2:** To determine participant satisfaction with each component of the intervention and identify opportunities for refinement of the intervention prior to testing in a larger study. *We hypothesize that the participants will adhere to 90% of the prescribed exercise sessions and that overall satisfaction will be high.*
- **Aim 3:** To establish that functional and objective assessments are feasible and well-tolerated in enrolled participants, as assessed using the functional fitness test (FFT) battery, dual-energy x-ray absorptiometry (DXA), finger-pricks for dried blood spots and patient-reported outcomes. *We hypothesize that these assessments will be well tolerated, as measured by the percent of participants who complete all measures and data from participant feedback questionnaires.*

2.3 Potential Risk and Benefits to Subjects

2.3.1 Known Potential Risks

Potential risks of participating in this study include musculoskeletal soreness and a possible loss of confidentiality, either through the breach of non-identifiable data collected online, or through the breach of secure study databases or physical files.

Potential Benefits of the Proposed Research to Human Subjects and Others: Findings from the proposed study will contribute to the scientific knowledge of the feasibility of resistance training interventions in endometrial cancer survivors. Additionally, the knowledge gained will contribute to the scientific knowledge aimed at understanding the potential therapeutic benefits of resistance training exercise for endometrial cancer survivors. The risks of our study procedures are low and therefore are seen as justifiable in regards to the knowledge to be gained.

Importance of Knowledge to be gained: Increasing physical activity after a cancer diagnosis is an important area of researching, and finding feasibly interventions for endometrial cancer survivors are key to sustainable lifestyle changes. This research will take the first step that will provide valuable information and serve as a scaffolding for the continued design and development of future interventions.

2.3.2 Protection against Risks

Study procedures will be reviewed and approved annually by the University of Wisconsin Health Sciences Institutional Review Board. Participants will be completing this intervention in their own home, and will be directed to stop exercising immediately if they experience any chest pains or abnormal symptoms such as dizziness, faintness, nausea etc. Additionally, in order to maximize participant safety and well-being, several strategies will be implemented to protect against and minimize any potential risks and to protect the privacy of all participants. Including:

- All participants will be screened with a telephone interview to determine their health status, eligibility, and ability to participate in aerobic exercise (Physical Activity Readiness Questionnaire; PAR-Q)
- Although the exercises will be completed at home, participants will be instructed to discontinue exercise if they experience any dizziness or light-headedness or pain in their chest. We will recommend that participants with continued issue to seek out their primary care physician.
- To minimize risks to confidentiality, participants will be assigned a study ID number to be used in place of their name. The only document linking study ID number and the participant's name will be kept separate from the data used for data processing and analysis. Only authorized study personnel will have access to the data. Electronic data will be coded and entered into a secured file on the Physical Activity Epidemiology lab server which is located in a password protected area with firewall protection and backed up daily. Moreover, the screening data for eligible participants will be kept and secured in a locked file cabinet in the Physical Activity Epidemiology lab until the participants has either completed the study, removed themselves from participation, or is excluded from participation. All screening data for eligible participants will be shredded upon participant completion, dropout, or exclusion from the study. Phone screening data from any interested potential participants not meeting inclusion criteria will be shredded immediately.
- If used, web-based surveys and their accompanying database will reside on a secure survey server. No private health information will reside on the survey server, only randomly generated ID numbers. Survey information will then be pulled into the secure database.

2.3.3 Potential Benefits to the Subjects

There are no anticipated benefits to the participants in this research study.

2.3.4 Risk Minimization:

No drug, biologic, or dietary supplement will be used in this study. To minimize risk, participants will undergo distal finger pricks to collect blood samples as opposed to traditional venipuncture for collection of blood biomarkers. No other laboratory tests will be conducted.

3 Study Aims

- **Aim 1:** To determine the feasibility of recruiting and retaining endometrial cancer survivors to a home-based resistance training 2 sessions per week of 20-40 minutes of exercise.
- **Aim 2:** To determine participant satisfaction with each component of the intervention and identify opportunities for refinement of the intervention prior to testing in a larger study.
- **Aim 3:** To establish that functional and objective assessments are feasible and well-tolerated in enrolled participants, as assessed using the functional fitness test (FFT) battery, dual-energy x-ray absorptiometry (DXA), finger-pricks for dried blood spots and patient-reported outcomes.

4 Study Design and Endpoints

4.1 General Design

- A phase III, randomized, two-arm trial with a wait-list control group
- The intervention itself is 10 weeks, with an additional five week follow up assessment for those in the exercise arm to determine adoption of the program. Overall, the anticipated total duration should be 20 weeks for participants
- The intervention will consist of (a) an initial in-person instructional session; (b) instructional materials and resistance training equipment (e.g., resistance bands) and (c) support and feedback provided via video coaching sessions; and (d) a final in-person study visit to collect post-study measures for both groups

4.1.1 Primary Study Endpoints

The primary endpoint is adherence to prescribed exercise sessions as measured using exercise logging and video sessions of exercises.

4.1.2 Secondary Study Endpoints

Secondary endpoints to be measured include qualitative satisfaction with intervention, blood biomarkers, lean muscle mass, body composition, functional fitness performance, self-efficacy, quality of life measures, and accelerometer-measured physical activity.

4.1.3 Primary Safety Endpoints

The primary safety endpoint will be total number of adverse events over the duration of the intervention.

5 Study Infrastructure

The general infrastructure for this study will include an overall PI (Dr. Lisa Cadmus-Bertram). There will be additionally one primary biostatistician for the study, and one main study coordinator who will be responsible for managing daily study operations.

6 Study Subjects – Enrollment and Withdrawal

- Accrual Goal: The study aims to enroll 40 participants over a one-year period. Subjects will be identified through their clinician/oncologist to determine interest in the study before being screened over the telephone by study staff.
- Participants will be screened over the phone to determine eligibility, and enrollment in the study will occur after screening by both the clinician/oncologist and research staff. The screening procedures will be performed under a separate screening consent form.

6.1 Subject Population

Age range of participants include ages 18-74 which is the range where diagnosis of endometrial cancer is most common. Because we intend to study adults, and not geriatric populations, the upper cap on the age for this study is 74 as to not dilute or modify the effect of resistance training in adults compared to elderly populations.

Women are the only participants in this study as endometrial cancer doesn't afflict men. No minorities or ethnic groups will be excluded from this study. We will recruit subjects without regard for minority status and ethnic status will be coded according to the Office of Management and Budget (OMG) Directive No. 15. The estimated ethnic/racial composition is presented in the Targeted/Planned Enrollment table and is representative of women in the geographic area of the proposed study (2010 Census Data for Madison, WI: 79% white, non-Hispanic; 7% African American; 7% Hispanic or Latino; 7% other ethnic/racial identities).

6.2 Inclusion Criteria

Inclusion Criteria	
1	Willing to provide written informed consent
2	Willing to comply with all study procedures and be available for the duration of the study
3	Fluent in spoken and written English
4	Women 18-74 years of age
5	Documented diagnosis of Type I, stage I-IIIc endometrial cancer within the past 5 years
6	Completion of current treatment for endometrial cancer, period of time of ≥10 weeks from treatment completion to study enrollment is required

6.3 Exclusion Criteria

Exclusion Criteria
1. Absolute contraindications to exercise (i.e., acute myocardial infarction, severe orthopedic or musculoskeletal limitations
2. Have evidence of recurrent or metastatic disease
3. Are currently performing resistance training ≥2 days per week
4. Report of chest pain, shortness of breath, fainting, or angina pectoris
5. Have physical disability that would limit range of motion through exercises such as sitting, standing and inability to walk one block
6. Plans to move from the area
7. Enrolled in another clinical trial or has used of any investigational drugs, biologics, or devices within 30 days prior to randomization
8. Women who are pregnant or breast-feeding
9. Not suitable for study participation due to other reasons at the discretion of the investigator

6.4 Subject Screening for Recruitment

6.4.1 Subject Identification

Participants will be recruited primarily through referrals at the research site. At the primary site, it will be UW-Madison's gynecologic oncology clinic, assisted by the UW Carbone Cancer Center's Gynecology Disease Oriented Team (DOT), a group that supports accrual to both collaborative and investigator-initiated clinical trials. Potentially eligible patients will be identified by the clinician after primary treatment has been completed and initial contact will be made by a member of the study team with endorsement of the medical care team. If needed, recruitment will be augmented via outreach through local cancer support organizations. Patients referred by their physician will be

contacted by study staff and screened for eligibility over the telephone. Self-referred participants will undergo telephone screening first, then eligibility will then be confirmed with the woman's physician. Recruitment methods will be the same between potential subject groups, i.e. same in treatment and wait-list control groups.

Additionally, members of the clinical care team may identify eligible cancer survivors from the electronic health record (EHR) and provide contact information for potentially eligible individuals to members of the study team. The study team will mail a letter to these individuals inviting them to participate, and providing them with information on how to contact the study team to enroll or to opt out.

Should we encounter difficulties with recruitment, we may accrue participants through community-based strategies including posting fliers at partnership organizations (such as Gilda's Club, for example). The primary mechanism of subject identification will be through referrals at the research site, but if necessary we may deploy community, word of mouth and flier-based recruitment.

6.4.2 Permission to Contact Form

Participants will be identified and recruited primarily through referrals at the research site, and prospective participants who are interested in the study will be asked to sign a Permission to Contact Form (Appendix 7) which allows members of the research team to contact them. Those who would like to be contacted to learn more about the study will sign the permission to contact from at the clinical site, and then those forms will be delivered to members of the research team to contact and screen for eligibility for the study. Once the permission to contact form is signed, the research team will take over to confirm eligibility, screen over the phone and enroll in the study.

6.4.3 Recruitment and Retention Strategies

Participants will be recruited primarily through referrals at the research site. If necessary, participants may be recruited through community partnerships through fliers and word of mouth recruiting.

Because the intervention is only 10 weeks in duration with a five week follow up, we do not anticipate major issues with participant retention. We have experience conducting several previous PA trials in cancer survivors and typically observe only ~5% loss to follow-up in a short-term study. To encourage retention, participants will receive $50 compensation at the baseline visit and again at the 10-week follow-up visit.

7.5 Vulnerable Populations

No vulnerable populations will be included in this study design.

TABLE 1: Vulnerable populations included and excluded from this study

Include	Exclude	Vulnerable Population Type
	X	Adults unable to consent
	X	Individuals who are not yet adults (e.g. infants, children, teenagers)
	X	Wards of the State (e.g. foster children)
	X	Pregnant women
	X	Prisoners

7.5.1 Subject Capacity

All subjects will have the capacity to give informed consent, else they will be excluded from this study.

7.6 Informed Consent

The PI will be responsible for ensuring that valid consent is obtained and documented for all subjects unless the IRB waives the requirement for documentation of informed consent for all or part of the study. Verbal consent will be given for the telephone screening questionnaire; however for the intervention, informed consent will be obtained during an in-person visit.

7.6.1 Process of Consent

- Consent will be obtained by either the PI, or by the Study Coordinator.
- Consent will be documented by having the participant sign the form, with a member of the study team signing to affirm the witnessing of the signing. One copy will be made and given to the participant, with another kept by the study team. Documentation will be stored in each participant's individual research file at the site's pre-determined storage location.
- Informed consent will be structured to be conducive to rational and thoughtful decision making by asking the prospective participant several questions about the intervention, including how to withdraw, how the groups will be allocated, what participation consists of, as well as what are the alternatives to participation.

7.6.2 Consent Form

The informed consent document for this study is maintained as a separate document.

7.6.3 HIPAA

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Attached/submitted as part of our application is a signed subject authorization form that includes information collected during this study as well as from medical record data will be used by the researchers and research staff as a part of this investigation. A HIPPA authorization form is attached to this protocol as an Appendix.

7.6.4 Revoking Consent

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

7.6.5 Costs to the Subject

There will be no costs to the participants for this study, any costs occurred during this research study will be covered by the grant funding mechanism.

7.6.6 Payment for Participation

Participants will be paid $50 in cash at the baseline visit as well as another $50 cash at the final (post-intervention) visit. Those who complete the intervention will receive a total of $100 cash.
At the instructional visit, participants will be provided with exercise equipment (towel, band, duffle bag, resistance bands, and dumbbells) that they will use for the intervention and will be allowed to keep after the intervention has completed. Any parking costs required for the in-person visits will be covered as a part of the study.

7.7 Early Withdrawal of Subjects

7.7.1 When and How to Withdraw Subjects

Participants may withdraw from the study prior to expected completion due to safety reason, losses to follow up, failure of subject to adhere to protocol requirements, subject consent withdrawal, etc.

7.7.2 Data Collection and Follow-up for Withdrawn Subjects

Data will be attempted to be gathered from participants who have withdrawn from the study to collect their data prior to their withdrawal, including emails from the research staff and telephone calls.

Withdrawn subjects will be analyzed using an intent to treat analysis, therefore maximizing the amount of data is paramount to success. However, if participants cannot be contacted after 3 attempts from the study team (both telephone calls and emails) then the participants will be considered lost to follow-up.

8 Study Procedures

Wait list interventions

After being randomized to the wait-list group, participants will be scheduled for their 10 week follow up visit. The wait list arm will not have the additional five week follow up that the exercise arm receives. Participants will be reminded that at that final visit, participants will complete the same study measures (body composition, functional fitness testing, blood sample collection, and anthropometrics) and will also receive study materials at the end of their wait list period. Participants in the wait list group will also complete accelerometer (Actigraph) assessments at three study points: Early in the intervention near the instructional visit, at the mid-way (5-week) mark, and before the final visit. These accelerometers will be sent and received via mail and participants will receive instructions on how to wear, use and send to us during the instructional visit.

Exercise interventions

After being randomized to the exercise (intervention) arm, participants will be scheduled for an instructional visit with the study coordinator within a week of randomization. At that visit, participants will be instructed to wear comfortable clothes and shoes for learning the exercises. The instructional visit includes going through each exercise of the intervention (see Table below) to learn the movement, learn the muscle groups involved, and to learn how to monitor themselves by tracking their progress via logs. This instructional visit should take 60-90 minutes, and each participant will receive a summary sheet of her starting point at each exercise with respect to intensity and progressions/regressions. For example, a participant may be starting on a blue resistance band for biceps curls, but the squats may simply be body weight at this time. Table below outlines the exercises for the intervention.

Table 2. Series of exercises, with progressions and regressions to increase/decrease difficulty.

Primary muscle group	Exercise	Progressions	Regressions
Thighs (quadriceps, hamstrings)	Body weight squats	• Add resistance band • Holding dumbbells	• Chair squats • Shortened range of motion
Calves (gastrocnemius, soleus)	Standing heel raises	• Holding dumbbells • Elevate ball of foot	• Shortened range of motion
Chest (pectoralis major & minor)	Standing chest press	• Increase band tension	• Reduce band tension
Back (trapezius, latissimus dorsii)	Seated banded row	• Standing row • Increase band tension	• Reduce band tension • Shorten range of motion
Abdominals (rectus & transverus adbominus)	Static v-sit hold with feet on floor	• Elevate feet • Add rotation • Add dumbbell	• Support with hands • Add lumbar support w/ towel
Shoulders (deltoids)	Seated banded press	• Standing • Use dumbbells	• Reduce band tension • Shorten range of motion
Biceps brachii	Seated banded curl	• Standing • Add tension to band • Use dumbbells	• Reduce band tension • Shorten range of motion
Triceps brachii	Seated arm extension	• Increase band tension	• Reduce band tension

During the study period, participants in the intervention arm will be instructed to complete the exercise routine twice a week for 10 weeks during the intervention, and also continued throughout the five week follow up period. There are eight video calls with the study coordinator to check in, to identify any issues or concerns with the exercises, and to finally monitor progress in the form of assessing volume/intensity/difficulty of each of the exercises. These calls are done over video so that the coordinator can build rapport with participants, and that participants can show

or demonstrate issues with exercises or their form. At the mid-point of the study, participants will receive an email with the questionnaires, so that the questionnaires will be done at baseline, at the study mid-point, and at the final visit.
Participants in the intervention group will also complete accelerometer (Actigraph) assessments at three study points: Early in the intervention near the instructional visit, at the mid-way (5-week) mark, and before the final visit. These accelerometers will be sent and received via mail and participants will receive instructions on how to wear, use and send to us during the instructional visit.
At the end of the 10 week period, participants will return to the UW campus for a final visit to repeat baseline study measures. At this time, intervention arm participants will also complete an exit-style interview with the study coordinator to help improve the intervention for future participants. This will be recorded, but anonymized upon transcription.
While the formal intervention period will be 10 weeks in duration, we will continue to follow those in the exercise arm for five weeks post-final assessment. This follow up period will consist of surveys to the participants assessing the frequency of the home-based resistance exercise, to determine if the behavior of exercise persists in the short-term following intervention conclusion.

8.1 Measures

Below are the study measures that will be collected over the course of the intervention:

- Demographics and other participant characteristics: Participants will self-report age, race/ethnicity, marital status, education, and cancer characteristics (tumor type and stage, dates of diagnosis and treatment completion, treatment received). Clinical information will be confirmed with the medical record.
    - **When collected:** Baseline
- Accelerometer. Although aerobic and lifestyle PA (e.g., MVPA, steps) are not a focus of the intervention, they will be assessed to determine baseline PA level and identify whether uptake of resistance training is associated with changes in other PA types. Participants will wear the ActiGraph wGT3X-BT accelerometer (ActiGraph, Pensacola, FL) for 7 days during all waking hours. The ActiGraph is a gold standard method of objective activity assessment.[26, 27]
    - **When collected:** Baseline, mid-point (~5 weeks), final visit (~10 weeks)
- Biomarkers. Using a standardized protocol, participants will undergo a fingerpick to collect a peripheral blood sample to assess glycosylated hemoglobin (A1c) and c-Reactive Protein[28] via dried blood spots. The values for both A1c and CRP are highly correlated between dried blood spots and venipuncture.[29]
    - **When collected:** Baseline, final visit (~10 weeks)
- Anthropometrics. Height, weight, waist and hip circumferences will be measured according to standard protocols.
    - **When collected:** Baseline, final visit (~10 weeks)
- Body composition. Resistance training can improve body composition even without weight loss. Body composition will therefore be assessed using dual-energy absorptiometry (DXA) using the enCORE Lunar iDXA software suite (GE Healthcare, Little Chalfont, UK). DXA provides a precise measure of fat mass, lean mass, total % body fat, and visceral fat and is sensitive to small changes from pre- to post-intervention.[30]
    - **When collected:** Baseline, final visit (~10 weeks)
- Functional fitness. The functional fitness test (FFT) is a battery of six tests measuring strength, flexibility, fitness, body composition, and agility. It has high test-retest reliability and is suitable for tracking within-person changes.[31] The functional fitness test battery includes the following 6 assessments: 1.) **The 30 second chair stand**, which assesses the strength of the lower body. Each person will have 30 seconds to stand up and sit down from a chair as many times as possible within the time frame. 2.) **The 30 second arm curl** assesses the strength of the upper body, where women will hold a 5 pound dumbbell in a seated position, and they will have 30

seconds to curl their arm and extend it as many times as possible within the time frame. 3.) The **6 minute walk test** measures the total distance that a person can quickly walk on a flat hard surface within a period of 6 minutes, using a 100ft length of distance. 4.) **The chair sit and reach** assesses the lower body flexibility where the participant will sit in a chair, extend one leg in front of them and flex at the waist, reaching toward their toes, and we will measure the distance between their toes and fingers. 5.) **The 8-foot-up and go** is an assessment of speed agility and balance. With this assessment, the participant begins in a seated position, and will be timed for the duration it takes to rise from the chair, walk as quickly as possible around a cone 8 feet away from the chair, and return to a seated position. 6.) **The back scratch test** is an assessment of the flexibility of the upper body, where the person will be seated and one arm will be flexed behind the head, and the other arm will be extended behind the shoulder. The assessment measures the distance between the finger tips of both hands.

    - **When collected:** Baseline, final visit (~10 weeks)

- Quality of life (QOL). QOL changes will be captured using the Functional Assessment of Cancer Therapies (FACT) questionnaire including the Endometrial subscale (FACT-En).[32] These measures will be repeated at the study mid-point (5 weeks) to assess changes over time.
    - **When collected:** Baseline, mid-point (~5 weeks), final visit (~10 weeks)
- Mental well-being. Changes in mental well-being (including anxiety, depression, and fatigue) will be assessed using standardized PROMIS measures.[33] These measures will be repeated at the study mid-point (5 weeks) to assess changes over time.
    - **When collected:** Baseline, mid-point (~5 weeks), final visit (~10 weeks)
- Self-efficacy. This will be assessed using the validated self-efficacy for exercise scale, modified for specificity to strength training.[34] These measures will be repeated at the study mid-point (5 weeks) to assess changes over time.
    - **When collected:** Baseline, mid-point (~5 weeks), final visit (~10 weeks)
- Adherence. Compliance and adherence will be measured via detailed exercise logs. A participant needs to complete at least 50% of the prescribed exercises in a session to be considered adherent to the session.
    - **When collected:** ongoing, logs will be completed throughout the intervention and submitted at the final visit
    - Additionally, for those in the intervention arm, we will ask that they continue to conduct the prescribed exercises for an additional five weeks after study completion. Participants will still submit paper logs, and this adherence measure will allow for study of adherence without prescribed check-ins from the study coordinator over the five week period.
- Acceptability. Participants will participate in a semi-structured qualitative interviews with the study coordinator. Interviews will be recorded, transcribed and coded to identify content themes. These interviews will be used to collect qualitative information and overall satisfaction with the intervention, as well as areas to improve with future interventions and barriers to participation.
    - **When collected:** Final visit (~10 weeks)

8.2 Video calls

Participants will receive a tablet for the duration of the intervention for video conferencing with research team. Phone call conferencing will be available, however the tablets allow for video applications so that participants can visually interface with members of the research team. Additionally, using video conferencing allows participants to receive feedback and form recommendations from her home if she has questions or would like feedback on her performance for specific exercises. However, because this is a pilot intervention, we aim to determine if the video

conferencing component is useful. By providing each participant with a tablet, we are inclusive for individuals who may not have access to these resources on her own. Each participant will receive a check-in at eight points during the 10 week study: two calls in the first week, one during weeks three four and five, one during week six , and finally one during week eight consistent with their preferred contact method to provide feedback on their progress and resistance training. The study coordinator will ask about overall qualitative satisfaction, and issues the participant is having, and any questions that the study coordinator could potentially address. Participants are welcome to reach out to the lab or study coordinator at any point during the study, however these pre-planned check in visits will hopefully facilitate discussion if any issues remain unaddressed.

8.3 Labs

Blood spots: In a non-clinical setting, dried blood spots collected using finger pricks are a low-cost way to establish the feasibility of biomarker data collection. Using a standardized protocol, participants will undergo a fingerpick to collect a peripheral blood sample to assess glycosylated hemoglobin (A1c) and c-Reactive Protein[50] via dried blood spots. Dried blood spots can be collected by non-phlebotomists in non-clinical settings, and the values for both A1c and CRP are highly correlated between dried blood spots and venipuncture.[51]

8.4 Established Standard of Care:

There are currently no established standards of care in terms of prescribing exercise (especially resistance training exercise) in endometrial cancer survivors.

Table 3. Study Calendar of scheduled measures

Modifications proposed

	Baseline	4-6 Weeks	10 Weeks	15 Weeks
Demographics	✓			
Cancer characteristics	✓			
Anthropometrics	✓		✓	
Body composition	✓		✓	
Biomarkers (blood spots)	✓		✓	
Physical activity (self-report)	✓	✓	✓	
Physical activity (device[1])	✓	✓	✓	✓
Functional fitness	✓		✓	
Quality of life	✓	✓	✓	
Self-efficacy	✓	✓	✓	
Satisfaction & feedback	✓	✓	✓	✓
Safety		✓	✓	✓

Additional data collected during intervention:
- Adherence logs (weekly)
- Coaching call completion

[1]We will be using accelerometers for data collection, as opposed to Fitbits in the original proposal, as accelerometers are the gold standard physical activity measure

8.5 Study Visits

8.4.1 Screening/Baseline:

Baseline. At this visit, the study coordinator will explain the study and obtain written informed consent. Physical measurements (anthropometrics, blood sample, DXA scan, functional fitness testing) will be completed. The study coordinator will instruct the participant on how to properly wear the accelerometer (to be returned via pre-paid mailer), complete a 7-day PA log, and complete the online questionnaires.

Randomization. After all baseline measures have been completed and checked, the participant will be randomized with 1:1 probability to the intervention or wait-list control group. A blocked randomization scheme will ensure equal allocation of participants to each group. Participants will be notified of their group assignment by phone; those in the intervention group will be scheduled for the intervention introductory session. (Those in the wait-list control group will receive this session at the same time as the final measures are collected.)

Instructional. Participants randomized to the intervention group will meet with study coordinator to learn how to conduct the exercises, how to use the materials, how to complete the exercise log and general instructions on the normal symptoms of resistance training. This visit should take 1-2 hours, ensuring the participant is confident.

8.4.2 Follow up:

Table 4. Acceptable Window for Study Visits (including weekends)

Visit	Window	Activities
Randomization	+/- 5 days	Allocate to group
Instructional visit	+/- 2 weeks	Teach exercises, learn how to interface with software, how to log exercises
Final visit	+ /- 2 weeks	Collect final measures

8.4.3 Unscheduled:

- Pain or concerns that need to be addressed in person
- Adverse event follow ups with PCP

8.4.4 Final Study Visit

Final Visit. All participants will return for follow-up assessments at 10 weeks. In advance, the participant will be mailed an accelerometer and 7-day PA log and will receive a link to complete the online questionnaires. Physical measures (anthropometrics, blood sample, DXA scan, functional fitness testing) will be completed. Those women in the wait-list control group will receive their introductory intervention session at this visit.

9 Study Analysis

9.1 Sample Size Determination

Sample Size and Power. The purpose of this trial is not to conduct hypothesis testing, but rather to field-test the intervention to identify adherence rates to exercise prescription across a group of participants. At this time, the anticipated effect size is unknown and the sample size of 40 has been selected to maximize feasibility in the anticipated time frame for this project.

9.2 Statistical Methods

As this is the first investigation in this population to look at this resistance training, both in terms of adherence rates as well as objective and functional changes in performance, there are no published effect sizes to anticipate at this time; therefore, we have a feasibility/descriptive focus as opposed to a hypothesis-testing focus. In addition to quantitative analysis, we plan to conduct qualitative analyses from participant feedback surveys to assess barriers to participation and to improve future interventions and to increase adherence rates.

9.3 Subject Population(s) for Analysis

The populations for this investigation include:

- All-randomized population: Any subject randomized into the study, regardless of whether they received study agent
- All-treated population: Any subject randomized into the study that received at least the instructional visit of the intervention
- Protocol-compliant population: Any subject who was randomized, was allocated to the exercise group and provided at least one set of data elements required by the protocol.

9.3.1 Describe the types of analysis:

- **Primary Analysis:** The primary objective includes measuring the percentage of completed sessions compared to prescribed, and a one-sample t-test will be conducted to determine if that proportion, across participants, is >90%. A one-sample t-test will be done to determine if retention is >90%.

- **Secondary Analyses:** The secondary analyses includes measuring the objective and functional changes from pre to post intervention as well as differences between groups. Paired ANOVAs and descriptive statistics will be used to analyze functional and objective data, as well as participant feedback data, including satisfaction with each component of the intervention.
- **Exploratory, longitudinal analyses:** Content analysis will be done on the qualitative interviews to examine barriers to physical activity, as well as satisfaction with the intervention, and identification of themes to improve the intervention. Although formal hypothesis testing is not part of our specific aims, we will conduct longitudinal analyses of the data we collect to estimate potential magnitude of expected changes, as well as longitudinal analysis of the repeated measures.
- **Safety Analysis:** The safety analysis includes simple descriptive analysis about the number of adverse events over the course of the intervention between groups and across sites.

9.4 Planned Interim Analysis:

There are no planned interim analyses for this investigation.

10 Data Collection, Handling and Record Keeping

10.1 Data Confidentiality

- We will take extensive measures to ensure data safety and security. A dedicated study database will be constructed on a secure server using the REDCap study management system.[56] To ensure quality control and appropriate completion of self-report measures, questionnaires will be collected online. Data quality will be checked by examining descriptive statistics and checking ranges of missing values.

10.1.1 Confidentiality of Subject Records

By signing the protocol, the Investigator agrees that *IRB and NCI* representative may consult and/or copy study documents in order to verify CRF data. By signing the consent form, the subject agrees to this process. If study documents will be photocopied during the process of verifying CRF information, the subject will be identified by unique code only and full names and similar identifying information (such as medical record number or social security number) will be masked.

The Clinical Site Investigators will ensure that the identity of subjects will be protected. All study records will be maintained in a secure fashion with access limited to essential study personnel only. All study documents submitted to the Coordinating Center will have identifiers removed other than dates of birth and service and subjects will be identified with a study-specific identification number only. The Clinical Site Investigators will maintain, in a secure location, an enrollment log that includes subject identifying information and links subjects to their study-specific identification number.

10.2 Data Capture

10.2.1 Missing Data

Strategies for handling missing data will be chosen based on the type and extent of the problem under advisement from biostatistician Dr. Gangnon. It is anticipated that sensitivity analyses or model-based approaches will be assessed for appropriateness for this investigation.

10.2.2 Data Collection Tools

UW-ICTR provides REDCap that will be used for data collection for this investigation. This tool is self-service, secure, and can be easily used across all study sites to ensure appropriate data collection. Additionally, this tool is buildable for the unique needs of this investigation, and we plan to use the participant as the unit of measure for this study, and not the time point as the unit of measure.

10.3 Records Retention

To ensure the integrity of the data collected from study participants, several procedures will be implemented. All personnel involved in data collection will be thoroughly trained in all assessment methods, thus ensuring consistent applications of procedures and measurement consistency across participants. All questionnaire data will be automatically saved in the secured, password protected Qualtrics or REDCap systems and will be downloaded to a password protected network folder on a secure server (i.e., password protected) which is backed up daily ensuring access only by the investigators. All other data will be saved to a computer hard drive in real time and then stored on a secure server (i.e., password protected) which is backed up daily. All raw data are kept in locked cabinets in the site-PI's laboratory. All hardcopies of raw data will be de-identified (with the exception of the study ID number) and copied for mailing to the coordinating center for data management. Although all packages with data will be mailed by certified mail so that tracking the location is possible, maintaining copies of the data at the collaborating centers in locked cabinets in the site investigator's laboratory will be done in the unlikely event that data is lost in the mail. Informed consent forms will be kept in a separate locked file cabinet with restricted access. Issues related to data integrity will be discussed on a weekly basis as a recurring agenda item in the weekly project meeting. Finally, continuing review of all procedures will be obtained by all appropriate institutional review boards.

Study data will be labeled with a study ID number. Data linking the study ID numbers with subject identities will be stored in hard copy format only. This and other paper files will be kept in a locked file cabinet in the Physical Activity Laboratory in the UW Department of Kinesiology (2000 Observatory Drive, Madison WI 53706, Room 2057). The laboratory door is kept locked at all times. Only study personnel will have access to participant data. Electronic data, including accelerometer data files, will be kept on a server at the Department of Kinesiology, in a drive accessible only by the PI and study staff. Data will be retained for an indefinite amount of time, and all study data will be banked in a coded format. Data may be used in the future for a secondary data analysis looking at relationships between collected study data and other variables. Study data may only be used by the study team, and all future investigations using any banked data from this study must undergo a separate IRB application. Use of study data is limited to the research team for this protocol, unless a separate IRB application is submitted for use of this banked data for future investigations.

10.4 Data and Safety Monitoring

The Site Investigator (Dr. Cadmus-Bertram) will be responsible for reviewing and monitoring all study data and any adverse events for this study. The Investigator will meet with study personnel at least weekly to evaluate study progress, including periodic assessment of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcomes. All unanticipated problems regardless of where they occur, will be reported to the University of Wisconsin IRB.

This protocol is considered to have a minimal risk to participants, as it prescribes physical activity that is consistent with national recommendations and guidelines for cancer survivors. We attempt to reduce the risk of injury or muscular soreness by excluding individuals who report difficulty transitioning from sitting to standing, walking 1 block (as a proxy measure of basic physical functioning), or report that they are otherwise unable to work towards the intervention goals. As with any exercise intervention, there is also a minor risk of cardiovascular events. Participants in both intervention groups will receive regular check-in calls to assess progress and address any potential problems regarding physical issues or emotional stress.

11 Assessment of Safety

This protocol is considered to have a minimal risk to participants, as it prescribes physical activity that is consistent with national recommendations and guidelines for cancer survivors. We attempt to reduce the risk of injury or muscular soreness by excluding individuals who report difficulty transitioning from sitting to standing, walking 1 block (as a proxy measure of basic physical functioning), or report that they are otherwise unable to work towards the intervention goals. As with any exercise intervention, there is also a minor risk of cardiovascular events. Participants in both intervention groups will receive regular check-in calls to assess progress and address any potential problems regarding physical issues or emotional stress.

12 Study Finances

12.30 Funding Source

This study is financed through an institutional pilot grant from the American Cancer Society and funds from the UWCCC.

12.31 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All UW investigators will follow the UW conflict of interest policy.

12.32 Subject Stipends or Payments

Participants will be paid $50 in cash at the baseline visit as well as another $50 cash at the final (post-intervention) visit. Those who complete the intervention will receive a total of $100 cash.

13 Publication Plan

The primary responsibility for publication of the results of this study are the investigators at UW Madison (Dr. Cadmus-Bertram). Neither the complete nor any part of the results of the study carried out under this protocol, nor any of the information provided by the sponsor for the purposes of performing the study, will be published or passed on to any third party without the consent of the study sponsor. Any investigator involved with this study is obligated to provide the sponsor with complete test results and all data derived from the study.

14 Protocol implementation timeline and contingency plans

There are three primary concerns for this research design and there are listed preliminary contingency plans if these concerns come to fruition:

- The primary concern is a lack of subjects or low accrual to study participant goals for site numbers.
    - If there is insufficient or slow recruitment through a clinical route, we plan to reach out to community support groups such as Gilda's Club to bolster recruitment numbers. This strategy will not replace the clinical route, but may increase participant enrollment.
- The secondary concern is high attrition in the treatment group and potential losses to follow up over the course of the 10-week intervention. Although this is a lower probability event, we will utilize the following contingency plans:
    - Deploy follow ups using a sufpport person for the participant that we can contact if the participant is not contacting study staff or seems to be lost to follow up
    - At the start of the study, we will collect multiple email addresses and phone numbers from

each participant to avoid this problem *a priori.*

- Finally, we may have poor adherence and compliance to the protocol.
    - We have pre-scheduled check-ins during the course of the intervention to avoid this issue
    - However, we will deploy additional health coaching if necessary where participants are really struggling with adherence
    - Participant satisfaction surveys will be used at the end of the intervention to evaluate the quality of the study to learn and improve for the future if adherence is very high

Table 5: Protocol implementation timeline for the home-based resistance training protocol in endometrial cancer survivors

	Pre-award	Year 1	Year 2
Protocol development			
PRMC/IRB Approval			
Recruitment			
Data collection			
Data analysis			
Manuscript preparation			
Data closeout protocols			
Manuscript publication			

Appendix 1: Participant tracking form: Checklist of Study Activities

Activity	Date completed	Staff initials
Screening call	/ /	
Baseline Assessments (all participants)		
Confirmation Letter sent	/ /	
Demographics and cancer characteristics	/ /	
Physical Measures (FFT and Anthropometrics)	/ /	
DXA Scan	/ /	
Blood biomarkers collected	/ /	
Questionnaire links emailed (5 questionnaires)	/ /	
Actigraph/instructions given	/ /	
Randomized to: ❍Intervention ❍Wait-list	/ /	
If intervention: Instructional visit scheduled	/ /	
Baseline Questionnaires verified	/ /	
Baseline incentive provided	/ /	
Instructional Visit (Intervention group)		
Date of visit – all exercises taught	/ /	
Participant exercise materials delivered	/ /	
ActiGraph data downloaded/checked	/ /	
Intervention materials provided (Both groups)	/ /	
Intervention Period (Intervention group)		
Date of first coaching call (1A)	/ /	
Date of second coaching call (1B)	/ /	
Date of week 2 coaching call (2)	/ /	
Date of week 3 coaching call (3)	/ /	
Date of week 4 coaching call (4)	/ /	
Actigraph mailed out	/ /	
Mid-point (5 week) Questionnaires Sent (5)	/ /	
Mid-point Questionnaires Verified	/ /	
Date of week 6 coaching call (6)	/ /	
Date of week 8 coaching call (8)	/ /	
Actigraph data downloaded/checked	/ /	

Final Assessments (all participants)		
Final visit scheduled	____/____/____	_____
ActiGraph mailed	____/____/____	_____
Questionnaire links emailed (5 questionnaires)	____/____/____	_____
Questionnaires verified	____/____/____	_____
Physical Measures (FFT and Anthropometrics)	____/____/____	_____
DXA Scan	____/____/____	_____
Blood biomarkers collected	____/____/____	_____
Accelerometer downloaded/checked	____/____/____	_____
Incentive delivered	____/____/____	_____
Qualitative interview with study coordinator	____/____/____	_____

Appendix 2: Demographic form

STUDY ID	HEALTH HISTORY AND DEMOGRAPHIC QUESTIONNAIRE	CURRENT DATE
_____		_____

Name: _____

Address: _____

City:_____**ZipCode:** _____

Phone:_____**Date of Birth:**_____**Current Age:** _____

Are you currently employed? (circle one): Yes No

What is your current job status? (Check all that apply).

- ☐ Employed full time (including self employed)
- ☐ Employed part time (including self employed) Hours/week: _____
- ☐ Volunteering full-time
- ☐ Volunteering part-time Hours/week: _____
- ☐ On leave of absence
- ☐ Retired (not due to health)
- ☐ Disabled and/or retired because of health
- ☐ Unemployed
- ☐ Student
- ☐ Homemaker- full time

Occupation: ____

Marital Status (circle one): Single Living with a partner/married

Education (circle highest level completed):

Elementary / High School / College / Some College / Graduate School

(PAGE 1 OF 2)

YOUR PAST HEALTH HISTORY

Circle any of the following medical conditions you have either been diagnosed with or have experienced.

High blood pressure	Stroke
Any heart problems	Blood Clots
Arthritis	Cancer
Diabetes	Liver or Kidney Disease
Recurring leg pain	Any breathing problems
Ankle swelling	
Low back or joint problems	

YOUR PRESENT HEALTH

Chest pain / discomfort Cough on exertion

Shortness of breath	Coughing of blood
Heart palpitations	Dizzy spells
Skipped heart beats	Frequent headaches
Heart Attack	Back Pain
Joint problems	Diabetes

Have you been hospitalized in the last year?
(circle one) Yes No

If YES, how many days were you in hospital? _____

Appendix 3: Exercise tracking log (example) for week 1 of 10 weeks

Week 1: Date Circle one: Day 1 OR Day 2

Exercise	Set 1		Set 2		Set 3 (Optional)	
	# Repetitions	RPE	# Repetitions	RPE	# Repetitions	RPE
Chair squats						
Dumbbell chest press						
Dumbbell single arm row						
Dumbbell shoulder press						
Standing heel raises						
Seated triceps extension						
Seated biceps curl						
Supported floor crunches						

Comments:_____

Concerns:_____

Week 1: Date Circle one: Day 1 OR Day 2

Exercise	Set 1		Set 2		Set 3 (Optional)	
	# Repetitions	RPE	# Repetitions	RPE	# Repetitions	RPE
Chair squats						
Dumbbell chest press						
Dumbbell single arm row						
Dumbbell shoulder press						
Standing heel raises						
Seated triceps extension						
Seated biceps curl						
Supported floor crunches						

Comments:_____

Concerns:_____

Appendix 5: Permission to Contact for Resistance Training Trial

You may be eligible for a study using a resistance training intervention in endometrial cancer survivors. Can research staff talk to you about their exercise study in endometrial cancer survivors?

The HIPAA Privacy Rule requires University of Wisconsin - Madison to obtain your written permission to release your name and phone number to Dr. Lisa Cadmus-Bertram and her research team at the University of Wisconsin-Madison so that they can contact you about taking part in this study. If you agree that we can share your name and telephone number, this information will only be used to contact you to provide more information about this study. Your name and telephone number will not be shared with anyone other than the UW research team. This permission for the researchers ends after the release of your health information to the researchers.

If you decide that you do not wish to take part in the research study after giving permission to provide the researchers with your name and telephone number, the UW researchers will destroy this information. Whenever possible, your health information will be kept confidential. However, if you have given permission to share your information with recipients who are not covered by federal health information privacy laws, the health information they receive may no longer be protected under those federal laws and the recipients may be permitted to further share your information without your permission. As noted before, there are no plans to share your name and contact information with anyone other than the UW researchers.

You do not have to give your name and contact information if you don't want to. If you don't want to provide your name and contact information, it will not affect your health care at this clinic.

By printing your name below and signing this form, you are giving permission for this clinic to give your name and telephone number to Dr. Lisa Cadmus-Bertram's research team to contact you about taking part in her study.

Your name: _____

Your signature: _____ Date: _____

Phone number: _____

Best time to call: _____

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