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TITLE: Exercise to Enhance Cardiovascular Health Among Black Prostate Cancer Patients with Androgen Deprivation Therapy: The POWER Trial

PRINCIPAL INVESTIGATOR: Christina Dieli-Conwright

CONTRACTING ORGANIZATION: Dana-Farber Cancer Institute, Boston, MA

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<b>13. SUPPLEMENTARY NOTES</b>								
<b>14. ABSTRACT</b> <b>The Exercise to Enhance Cardiovascular Health among Black Prostate Cancer Patients with Androgen Deprivation Therapy (The POWER Trial)</b> is a multi-center, two-armed, pilot randomized controlled trial to compare a 16-week, thrice-weekly, virtually supervised, exercise intervention versus usual care in 62 Black men with PCa undergoing ADT. The exercise intervention will be culturally tailored (e.g., accessible virtual/home-based exercise, monthly group exercise sessions, biweekly newsletters, an in-person orientation session, and Black PCa support group meeting), and home exercise equipment, fitness trackers, and an internet-enabled tablet will be provided at no cost for one-on-one virtually supervised exercise sessions. The usual care group will be offered to receive the same exercise program after the 16-week intervention period.								
<b>15. SUBJECT TERMS</b> None listed.								
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## Introduction

**Prostate cancer (PCa) is the most common cancer among, accounting for nearly 200,000 new cases and nearly 30,000 deaths each year.** However, unsettling cancer health disparities persist against Black men where they are 1.8 and 2.2 times more likely to develop and die of PCa compared to White men. One standard treatment for PCa is androgen deprivation therapy (ADT) which reduces or eliminates circulating levels of the male hormones (i.e., testosterone) that stimulate cancer cells to grow. However, Black PCa patients present with compromised overall survival after receiving ADT, likely due to the complications of ADT (e.g., metabolic dysregulation) and the development of comorbidities such as cardiovascular disease (CVD) rather than cancer progression itself. Exercise during ADT is an effective intervention that improves physical fitness/function and body composition, cardiometabolic biomarkers, and quality of life, and reduces the side effects of ADT treatment. Nonetheless, previous clinical trials for exercise in PCa survivors were mostly conducted in non-Hispanic White patients and disproportionately underrepresenting racial/ethnic minorities. Notably, recent studies showed that Black PCa patients receiving ADT are more susceptible to developing CVD because they have a high prevalence of pre-existing dyslipidemia (i.e., 37%) or diabetes (i.e., 29%) before starting ADT and of significantly elevated CVD-related blood markers during ADT. Nevertheless, the feasibility and efficacy of exercise cannot be simply generalized to Black PCa patients due to potential biological, cultural, and socioenvironmental factors. ***Thus, culturally-tailored exercise programs for Black PCa patients on ADT, aiming to manage their elevated CVD risks as well as improve health-related fitness outcomes and patient-reported psychosocial and treatment symptom outcomes, have a significant potential to improve long-term health outcomes and address the cancer health disparities in this vulnerable population.*** We hypothesize that the exercise intervention will reduce CVD risk factors (primary endpoint), improve physical fitness and body composition, and patient-reported outcomes (i.e., quality of life and treatment symptoms), compared with usual care. The objectives of our proposed study is to compare a 16-week, thrice-weekly, remotely supervised, exercise intervention (N=31) versus usual care (N=31) among Black men with PCa undergoing ADT on (1) **CVD risk factors**, (2) **fitness outcomes** and **patient-reported outcomes**, and (3) to explore the **longer-term effects** of exercise on study outcomes at one-year follow-up.

**SPECIFIC AIMS.** Our proposed study has the following four aims:

**Specific Aim 1:** To examine the effects of the exercise intervention on CVD risk factors among Black men with PCa undergoing ADT, assessed by the Framingham Risk Score, an established composite score for assessing the risk of developing CVD, which will be calculated using six categories (age, low-density lipoprotein-cholesterol or total cholesterol, high-density lipoprotein-cholesterol, blood pressure, and diabetic and smoking status).

**Specific Aim 2:** To examine the effects of exercise on cardiorespiratory capacity (i.e., peak oxygen consumption), muscular strength (1-repetition maximum), and body composition (i.e., lean body mass and body fat mass).

**Specific Aim 3:** To examine the effects of exercise on health-related quality of life, treatment side effects, and psychosocial outcomes using validated self-reported questionnaires.

**Specific Aim 4:** To explore the longer-term effects on CVD-risk factors, fitness outcomes, patient-reported outcomes, and clinical outcomes at 1-year follow-up.

**The Exercise to Enhance Cardiovascular Health among Black Prostate Cancer Patients with Androgen Deprivation Therapy (The POWER Trial)** is a multi-center, two-armed, pilot randomized controlled trial to compare a 16-week, thrice-weekly, virtually supervised, exercise intervention versus usual care in 62 Black men with PCa undergoing ADT. The exercise intervention will be culturally tailored (e.g., accessible virtual/home-based exercise, monthly group exercise sessions, biweekly newsletters, an in-person orientation session, and Black PCa support group meeting), and home exercise equipment, fitness trackers, and an internet-enabled tablet will be provided at no cost for one-on-one virtually supervised exercise sessions. The usual care group will be offered to receive the same exercise program after the 16-week intervention period.

**Keywords:** Cancer health disparities, prostate cancer, exercise, cardiovascular disease, Black men

## Accomplishments

- Major objectives and accomplishments per approved SOW:

	Timeline	Research Sites	
	Months	DFCI	BIDMC
<b>Specific Aim 1, 2, &amp; 3: To examine the effects of the exercise intervention among Black men with PCa undergoing ADT on (1) CVD risk factors, (2) physical fitness and body composition, and (3) health-related quality of life, treatment side effects, and psychosocial outcomes.</b>			
<b>Major Task 1: Preparation of Research Regulatory Documents and Logistics- COMPLETED</b>			
Subtask 1: Refine eligibility criteria, exclusion criteria, screening protocol- <b>COMPLETED</b>	1	CDC, PN, TR, HU	DE
Subtask 2: Finalize consent form & human subjects protocol- <b>COMPLETED</b>	1-2	CDC, PN, TR, HU	DE
Subtask 3: Coordinate with Sites for IRB protocol submission- <b>COMPLETED</b>	1-2	CDC	DE
Subtask 4: Clinicaltrial.gov registration- <b>COMPLETED</b>	1-2	CDC	
Subtask 5: Submit amendments, adverse events and protocol deviations as needed- <b>COMPLETED</b>	As Needed	CDC	DE
Subtask 6: Coordinate with Sites for annual IRB report for continuing review- <b>COMPLETED</b>	Annually	CDC	DE
Subtask 7: Develop research protocol- <b>COMPLETED</b>	1-3	CDC, PN, TR, HU	DE
Subtask 8: Coordinate with Sites for flow chart for all study steps, data collection and database requirements- <b>COMPLETED</b>	1-3	CDC, PN, TR, HU	DE
Subtask 9: Finalize assessment measurements- <b>COMPLETED</b>	1-3	CDC, PN	DE
<i>Milestone Achieved:</i> IRB approval, trial registration, and research protocol development- <b>COMPLETED</b>	3	CDC, PN, TR, HU	DE
<b>Major Task 2: Participant Recruitment, Therapy, Participant Evaluation- IN PROGRESS</b>			
Subtask 1: Begin subject recruitment- <b>COMPLETED</b>	4-19	CDC, PN	DE
Subtask 2: Complete baseline assessments- <b>IN PROGRESS</b>	4-19	CDC	
Subtask 3: Deliver of intervention- <b>IN PROGRESS</b>	4-19	CDC	
Subtask 4: Complete post-intervention assessments after 16 weeks from baseline- <b>IN PROGRESS</b>	8-24	CDC	
<i>Milestone Achieved: Completion of participant enrollment, intervention delivery, and baseline and post-intervention assessments (Timepoints 1 &amp; 2)- IN PROGRESS</i>	24	CDC, PN	DE
<b>Major Task 3: Data Analysis- NOT YET PERFORMED</b>			
Subtask 1: Perform all analyses according to specifications- <b>NOT YET PERFORMED</b>	25-26	CDC, HU	
Subtask 2: Share output and finding with all investigators- <b>NOT YET PERFORMED</b>	27	CDC, PN, TR, HU	DE
Subtask 3: Work with data core and dissemination of findings (abstracts, presentation, publications, DOD) - <b>NOT YET PERFORMED</b>	28-36	CDC, PN, TR, HU	
<i>Milestone Achieved: Report results from data analyses- NOT YET PERFORMED</i>	28-36	CDC, HU	
<b>Specific Aim 4: To explore the longer-term effects on CVD-risk factors, fitness outcomes, patient-reported outcomes, and clinical outcomes at 1-year follow-up.</b>			
<b>Major Task 1: Follow-up Assessments- NOT YET PERFORMED</b>			
Subtask 1: Complete follow-up assessments after one-year from baseline	16-31	CDC	
<i>Milestone Achieved: Completion of follow-up assessments (Timepoint 3)</i>	16-31	CDC	

<b>Major Task 2: Data Analysis (follow-up) - NOT YET PERFORMED</b>			
Subtask 1: Perform all analyses according to specifications- NOT YET PERFORMED	31	CDC, HU	
Subtask 2: Share output and finding with all investigators- NOT YET PERFORMED	32-33	CDC, PN, TR, HU	DE
Subtask 3: Work with data core and dissemination of findings (abstracts, presentation, publications, DOD) - NOT YET PERFORMED	34-36	CDC, PN, TR, HU	
<i>Milestone Achieved: Report results from data analyses-</i> NOT YET PERFORMED	34-36	CDC, PN, TR, HU	

- Opportunities for training and professional development. Nothing to report.
- Results disseminated to communities of interest. Nothing to report.
- Plans for next reporting period. The focus for the upcoming reporting period will be on Major Task 2 of Specific Aims 1-3 as we increase enrollment, data collection, and intervention delivery.

**Impact.** Nothing to report.

**Changes/Problems.** Nothing to report.

**Products.** The protocol abstract was delivered as a poster presentation at the 2023 American Society for Clinical Oncology in June 2023:

Kang DW, Einstein DJ, Nguyen PL, Rebbeck TR, Uno H, Mossanen M, Morgans AK, Wilson RL, Gonzalo-Encabo P, Ficarra S, Gardiner J, Tjogas D, **Dieli-Conwright CM**. Exercise to Enhance Cardiovascular Health among Black Prostate Cancer Patients with Androgen Deprivation Therapy: The POWER Trial. American Society of Clinical Oncology (ASCO) Annual Meeting, 2023, Chicago, IL.

#### **Participants & Other Collaborating Organizations.**

- Individuals working on the project include the following.

<b>Name</b>	Christina Dieli-Conwright
<b>Project Role</b>	PI
<b>Research Identifier</b>	<a href="https://orcid.org/0000-0001-9093-7259">https://orcid.org/0000-0001-9093-7259</a>
<b>Nearest person month worked</b>	2.4 CM
<b>Contribution to Project</b>	Dr. Dieli-Conwright oversees all aspects of the trial including staff management.
<b>Funding Support</b>	NIH, DOD, Pfizer, ACS, AICR, Institutional Support

<b>Name</b>	Timothy Rebbeck
<b>Project Role</b>	Co-Investigator
<b>Research Identifier</b>	<a href="https://orcid.org/0000-0002-4799-1900">https://orcid.org/0000-0002-4799-1900</a>
<b>Nearest person month worked</b>	0.6 CM
<b>Contribution to Project</b>	Dr. Rebbeck provides insight into trial management and outreach resources.
<b>Funding Support</b>	NIH, DOD, Institutional Support

<b>Name</b>	Paul Nguyen
<b>Project Role</b>	Co-Investigator

<b>Research Identifier</b>	<a href="https://orcid.org/0000-0003-4268-3973">https://orcid.org/0000-0003-4268-3973</a>
<b>Nearest person month worked</b>	0.6 CM
<b>Contribution to Project</b>	Dr. Nguyen provides insight into trial management and medical oncology screening.
<b>Funding Support</b>	DOD, Institutional Support

<b>Name</b>	Hajime Uno
<b>Project Role</b>	Co-Investigator and Biostatistician
<b>Research Identifier</b>	<a href="https://orcid.org/0000-0003-0622-8471">https://orcid.org/0000-0003-0622-8471</a>
<b>Nearest person month worked</b>	0.6 CM
<b>Contribution to Project</b>	Dr. Uno provides statistical support, notably randomization given the stag of research.
<b>Funding Support</b>	NIH, DOD, ACS, Institutional Support

<b>Name</b>	Mary Norris
<b>Project Role</b>	Project Manager
<b>Research Identifier</b>	Ms. Norris leads the logistical activities of the data collection and recruitment processes.
<b>Nearest person month worked</b>	0.6 CM
<b>Contribution to Project</b>	N/A
<b>Funding Support</b>	NIH, ACS, DOD

<b>Name</b>	Dong-Woo Kang
<b>Project Role</b>	Postdoctoral Fellow
<b>Research Identifier</b>	Dr. Kang oversees the intervention delivery including progression and tolerance of exercise.
<b>Nearest person month worked</b>	3.0 CM
<b>Contribution to Project</b>	N/A
<b>Funding Support</b>	NIH, DOD, Pfizer, PCF

<b>Name</b>	Danny Nguyen
<b>Project Role</b>	Clinical Research Coordinator
<b>Research Identifier</b>	Mr. Nguyen aids in data collection and patient scheduling alongside Ms. Norris.
<b>Nearest person month worked</b>	1.2 CM
<b>Contribution to Project</b>	N/A
<b>Funding Support</b>	NIH, DOD, Pfizer, ACS

<b>Name</b>	Rebekah Wilson
<b>Project Role</b>	Postdoctoral Fellow
<b>Research Identifier</b>	<a href="https://orcid.org/0000-0003-1704-3624">https://orcid.org/0000-0003-1704-3624</a>
<b>Nearest person month worked</b>	3.0 CM
<b>Contribution to Project</b>	Dr. Wilson oversees treatment and data collection fidelity with oversight of staff training.
<b>Funding Support</b>	Institutional Support

- Change in the active other support of the PI. Nothing to report.

- Other organizations involved as partners include the following:
  - Organization name: Beth Israel
  - Partner's contribution to the project:
    - Financial support. Dr. David Einstein will be provided effort upon final approval of subcontract set up.
    - In-kind support. Nothing to report.
    - Facilities. Nothing to report.
    - Collaboration. Dr. Einstein directly refers eligible patients to the DFCI team via email and joins study team meetings for input on study design and recruitment.
    - Personnel exchanges. Nothing to report.

**Special Reporting Requirements.** Nothing to report.

**Appendices.** Nothing to report.