Informed consent form

Official study title: Effect of combined training on quality of life, functional capacity, cardiovascular function, and body composition in prostate cancer patients undergoing androgen suppression therapy: a randomized controlled clinical trial.

Ethics committee approval date: 29 April 2026

Date of last revision: 25 June 2026

Research Project Data

Research Title: Effect of supervised multicomponent physical exercise on quality of life, functional capacity, cardiovascular function, and body composition in prostate cancer patients undergoing androgen suppression therapy: a randomized controlled clinical trial

Researcher:: Cíntia de la Rocha Freitas

Version: 2

CAAE: 95978626.5.0000.0121

Proposing Institution: UNIVERSIDADE FEDERAL DE SANTA CATARINA

Approval date: April, 29 of 2026

RESEARCH PROJECT DATA

Review Number: 8.392.264

REVIEW DETAILS:

The information listed in the sections “Project Presentation,” “Research Objective,” and “Risk and Benefit Assessment” was extracted from the Basic Research Information file (PB_INFORMAÇÕES_BÁSICAS_2569907.pdf, dated April 9, 2026) and/or from the Detailed Project/Investigator’s Brochure.

This is a unicenter, parallel, randomized controlled clinical trial with 1:1 allocation, superiority design, and blinded evaluators, aiming to evaluate the effect of supervised physical exercise in men with prostate cancer undergoing androgen suppression therapy. Participants will be randomized into an intervention group (multicomponent training involving strength, aerobic capacity, coordination, and flexibility, lasting 60 minutes, three times per week, for 12 weeks) and a control group (usual activities). Outcomes include quality of life, functional capacity, cardiovascular parameters, body composition, and physical activity level, assessed before and after the intervention.

After completion of the study, both groups will be invited to participate free of charge in extension projects involving physical exercise for oncology patients at the Sports Center of the Federal University of Santa Catarina.

This is a postdoctoral fellowship within the Graduate Program in Physical Education.
Participating center: Oncology Research Center (CEPON) – Marcelo
Inclusion criteria:
a) present stages I to III of prostate cancer (PC), as certified by the physician in the medical record;
b) be undergoing androgen suppression therapy (AST);
c) be 40 years of age or older;
d) provide a medical certificate authorizing participation in both the intervention and the assessments;
f) not have participated in physical exercise research or any type of systematic physical exercise intervention during the four months prior to the intervention;
g) reside in the Greater Florianópolis region, Santa Catarina, Brazil.

Research Objectives

Primary Objective: Evaluate the effect of supervised multicomponent physical exercise on quality of life, functional capacity, cardiovascular parameters, body composition, and physical activity level in prostate cancer patients undergoing AST.

Secondary Objectives: Compare intra- and intergroup effects before and after intervention on:

Quality of life components (fatigue, pain, anxiety, depression, global health, functionality, vitality, emotional limitations, social aspects, mental health, cognitive function, insomnia, etc.).

Functional capacity (cardiorespiratory fitness, lower limb strength, agility, flexibility, handgrip strength).

Cardiovascular parameters (blood pressure, resting heart rate, flow-mediated dilation, arterial stiffness, carotid intima-media thickness, heart rate variability).

Physical activity level.

Body composition (fat percentage, lean mass, bone mineral density).

Risk and Benefit Assessment

Risks: Possible fatigue, muscle pain, dizziness, or discomfort during exercise. All sessions will be supervised by trained professionals and immediately interrupted if symptoms occur. Participants will be referred to the University Hospital or emergency care if necessary. Exercises will follow safe protocols respecting health conditions.

Benefits: Potential improvements in physical disposition, functional capacity for daily activities, aerobic capacity, muscle strength, balance, flexibility, joint mobility, metabolic profile, disease control, psychological well-being, and overall quality of life. The study also contributes to the development of exercise programs for prostate cancer patients under AST.

Comments and Considerations
All pending issues in the informed consent form (ICF) have been resolved. A new ICF has been presented along with a response letter to the previous review.

Conclusion

No pending issues remain. The project is approved.

Final Considerations by the Ethics Committee
This opinion was based on the submitted documents, including the detailed project, investigator's brochure, informed consent form, and institutional approval.

Review Status: Approved
CONEP Review Required: No

Location: Florianópolis, April 29, 2026

Signed by: Luciana C. Antunes (Coordinator)

Assinado por:
Luciana C Antunes
(Coordenador(a))