

ABSTRACT

Introduction: Active surveillance (AS) is the preferred primary treatment strategy for men with low risk clinically localized prostate cancer; however, the majority of these men still receive radical treatment within 10 years due to disease progression and/or fear of cancer progression. Interventions designed to suppress tumour growth, mitigate fear of cancer progression, and precondition men for impending radical treatments are an unmet clinical need. Exercise has been shown to delay the progression of prostate tumours in animal models, improve physical and functional health, and manage psychological outcomes in cancer patients; however, these outcomes have not been demonstrated in prostate cancer patients undergoing AS.

Methods and Analysis: This phase II randomized controlled trial will randomize 66 men undergoing AS to either an exercise group or usual care group. The exercise group will perform a 12-week, supervised, high-intensity interval aerobic exercise program, consisting of 3 sessions/week for 28-40 minutes/session. The primary outcome will be cardiorespiratory fitness. Secondary outcomes will include immunosurveillance- and cancer-related biomarkers, psychosocial outcomes including fear of cancer progression and quality of life, and physical function. Exploratory outcomes will include progression to radical treatment. The trial has 80% power to detect a significant between-group difference in VO_{2peak} of 3.5 ml/kg/min with a two-tailed alpha level of less than 0.05 and a 10% drop-out rate.

Ethics and dissemination: The study has received full ethical approval from the Health Research Ethics Board of Alberta – Cancer Committee (Protocol #: HREBA.CC-17-0248). The findings of the study will be disseminated through public and scientific channels.