

Intense exercise for survival among men with metastatic prostate cancer: 12 months feasibility results from the INTERVAL-GAP4 trial.

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Background: Exercise is now considered an important therapy to ameliorate treatment side effects, improve quality of life and physical function however, causation of survival benefit and the underlying mechanisms is not yet established. In 2015, the Intense Exercise for Survival among Men with Metastatic Castrate-Resistant Prostate Cancer (INTERVAL-GAP4) – a world-wide multicentre phase III trial – was launched to determine if high-intensity combined resistance and aerobic exercise plus psychosocial support improves overall survival in men with metastatic prostate cancer. Here, while exercise delivery and follow-up assessments are still taking place in 6 different countries, we aim to examine the feasibility, exercise compliance and safety of a 12-month exercise medicine program in patients with mCRPC. **Methods:** Experimental design was a longitudinal analysis of attrition rates, exercise attendance and compliance metrics and programme safety over the initial 12 months of patients participating in the INTERVAL-GAP4 trial at the Edith Cowan University site in Perth, Australia. **Results:** 201 patients were screened for participation and 46 patients (22.9%) were randomly assigned to the two study arms. Median time since prostate cancer diagnosis was 72.0 (interquartile range (IQR): 19.5–118.5) months. Most patients were previously treated with radiotherapy (53.3%). Metastases present mostly in the lymph nodes (53.3%), followed by bones (51.1%), lungs (2.2%) and bladder (2.2%). Participants attended a total of 2,907 out of 3,744 exercise sessions scheduled, with a median exercise attendance of 78.8% (IQR: 71.6%–82.7%) per participant. Majority of sessions were performed at an RPE of 7–8 indicating “vigorous intensity” or at an RPE of 5–6 indicating “moderate intensity” (67.2%). Tolerance was moderate-to-high in most sessions (83.0%). 191 adverse events (AEs) were observed throughout the study period. A total of 136 adverse events were reported by 19 participants from the exercise group, and these were mainly disease related (n= 69, 50.7%). Most AEs were grade 1 and 2 (n= 126, 92.7%). In the control group, 55 AEs were observed, and these were mainly disease related (n= 22, 40.0%) and grade 1 and 2 (n= 51, 92.7%). The most common intervention-related adverse events experienced in the exercise group were pain (n= 6, 50.0%; i.e., back pain, bone pain, lymph node pain, and general pain). **Conclusions:** Patients with mCPRC can participate in high-intensity aerobic and resistance training with moderate to high attendance and tolerance. The exercise intervention appears safe with limited intervention-related adverse events experienced and mostly minor and expected. However, with only 22.9% of screened patients deemed suitable and willing, this aspect of feasibility requires attention. Clinical trial information: NCT02730338. Research Sponsor: Movember Foundation.