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Prostate Cancer

# Feasibility and Implementation of INTERVAL-GAP4: A Global Randomised Controlled Trial of Intense Hybrid-supervised/Self-managed Versus Self-directed Exercise for Metastatic Prostate Cancer

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**Abstract**

***Background and objective:*** Physical activity is associated with a lower risk of mortality in men with prostate cancer (PC); yet, randomised controlled trials with survival endpoints are nonexistent. INTense ExeRcise for surviVAL-Global Action Plan 4 (INTERVAL-GAP4) was a global phase 3 trial designed to test whether structured, hybrid-supervised/self-managed exercise improves survival in men with metastatic PC. The trial was stopped early due to poor accrual. This paper reports feasibility and implementation outcomes.

***Methods:*** Men with metastatic PC were randomised (1:1) to a supervised/self-managed moderate- to high-intensity resistance and aerobic programme (three

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Intervention
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Metastasis
Survival

sessions per week for 2 yr) or to self-directed exercise. We evaluated site activation, recruitment, year 1 adherence, adverse events, and barriers to global trial feasibility. Efficacy outcomes—including survival, physical fitness, and biomarker results—will be reported separately.

***Key findings and limitations:*** Of 21 activated sites across seven countries, 13 (62%) randomised patients. Of 938 patients approached, 232 (25%) consented and 145 (15%) were randomised (75 in the intervention and 70 in the control group) between April 2016 and February 2023. The median age was 70 yr (range: 44–89 yr). The study closed early after reaching 17% of the intended target. The median adherence in the intervention arm was 84% (interquartile range: 61–95%), with no difference between metastatic castrate-resistant and hormone-sensitive PC. At 12 mo, 58% of intervention participants met exercise guidelines versus 24% of controls. In year 1, 162 adverse events occurred in the intervention group and 109 in the control group; 19 adverse events were study related, all in the intervention arm. The major feasibility challenges included administrative burden, infrastructure limitations, logistics of supervised exercise delivery, and coronavirus disease 2019 disruptions.

***Conclusions and clinical implications:*** While high adherence to a demanding exercise programme was achieved in selected metastatic PC patients, global recruitment proved difficult. Future large-scale exercise-oncology trials require streamlined protocols, realistic timelines, and greater alignment with site resources. Implementation science research is needed to support integration of exercise into routine advanced cancer care. A forthcoming paper will present the trial's survival and physical fitness efficacy outcomes.

***Patient summary:*** In this report, we describe the feasibility of a centrally coordinated, global clinical trial of hybrid-supervised/self-managed versus self-directed exercise for men with metastatic prostate cancer. We report trial implementation as mixed across the world, while exercise session adherence was high among men receiving the intervention. However, of the patients approached, 53% declined to participate in the study, and those enrolled were likely more motivated and willing to exercise. Those who participated varied in age, had other health conditions, were receiving multiple medications, and were at different treatment stages after a diagnosis of metastatic prostate cancer. Recent guidelines provide a framework for integrating exercise programming into clinical care for patients with advanced cancer. Further implementation science research is needed to help patients with advanced cancer exercise safely and effectively as part of their cancer care.



## 1. Introduction

Physical activity after a prostate cancer (PC) diagnosis is associated with longer patient survival [1–4], with a 31% reduced risk of cancer-specific mortality (summary relative risk = 0.69; 95% confidence interval [CI]: 0.55–0.85) [5] and a 40% risk reduction for all-cause mortality (hazard ratio [HR]: 0.60; 95% CI: 0.46–0.79) [6], comparing the most active versus least active PC survivors from cohort studies. In 2015, Movember funded the global phase 3 randomised controlled trial (RCT) INTense ExeRcise for surviVAL-Global Action Plan 4 (INTERVAL-GAP4) to determine whether a prescribed hybrid-supervised/self-managed model of moderate- to high-intensity aerobic and resistance exercise improves overall survival (primary outcome) compared with a self-directed exercise control, in men with metastatic PC [7]. The trial was stopped early because of poor accrual in 2023. This paper reports the feasibility of INTERVAL-GAP4 global study implementation, including challenges of study recruitment and feasibility of completing the 1st year of a hybrid-supervised exercise intervention relative to self-directed exercise. This manuscript focuses exclusively on feasibility and implementation outcomes. Analyses of efficacy, including overall survival, physical fitness, and biomarker endpoints, are on-going and will be reported in separate publications.

## 2. Patients and methods

### 2.1. Study design

INTERVAL-GAP4 was a multicentre phase 3 RCT (ClinicalTrials.gov: NCT02730338), with the study protocol reported elsewhere [7]. INTERVAL-GAP4 compares hybrid-supervised/self-managed (supervised tapering to self-management) aerobic and resistance exercise (intervention) with self-directed exercise via print materials (control), over 2 yr with follow-up for overall survival (primary out-

come) and multiple secondary outcomes (ie, time to disease progression, physical fitness, quality of life, biomarkers of inflammation, energy metabolism, and androgen metabolism). Participants were randomised using a central database (REDCap; Vanderbilt University, TN, USA) with block randomisation (blocks of 2, 4, and 6) and stratified by treatment status (Supplementary Table 1) using the R package blockrand. Allocation sequence was concealed.

### 2.2. Participants

INTERVAL-GAP4 aimed to recruit 866 men with metastatic PC (46 patients per site, >20 activated sites). The eligibility criteria based on the final protocol version are provided in Supplementary Table 1. Original criteria (from enrolment in 2016) are provided in boxes 1 and 2 of the published protocol [7]. Initially, men with metastatic castrate-resistant PC (mCRPC) were eligible if they were (1) on abiraterone and/or enzalutamide and stable, or (2) abiraterone and enzalutamide naïve. Clinical eligibility was expanded in protocol versions 2–4 (September 2015, July 2016, and April 2018) to accommodate the variations in the standard of care and treatment sequencing in mCRPC worldwide, and to optimise global recruitment. Protocol version 5 (October 2019) included men with metastatic hormone-sensitive PC (mHSPC) and allowed remotely monitored exercise (exercise with asynchronous remote monitoring of heart rate data and weekly phone check-in) to address slow accrual and improve participant convenience. After confirmation of clinical eligibility and informed consent, participants were required to pass a medically supervised cardiopulmonary exercise test (CPET) with electrocardiogram (ECG) to ensure patient safety prior to vigorous exercise required on study. All sites obtained ethics approval.

### 2.3. Intervention

High-intensity interval and moderate-intensity continuous aerobic exercise was combined with moderate-to-high load resistance exercise for 3 d/wk across 96 wk (24 × 4-wk cycles, approximating 2 yr). The programme was progressive, periodised, and autoregulated and included a deload week (ie, reduced exercise volume and intensity) each 4-wk cycle. Periodisation (cycles) to optimise adaptation and autoregulation are programmatic principles facilitating exercise participation for people who experience variations in treatment tolerance, toxicity, and disease control, thus requiring additional recovery after sustained periods of exercise [8,9]. As such, exercise sessions were modifiable to accommodate changes in participant presentation, symptomology, and known bone metastasis locations [10–14]. In year 1 (48 wk), participants were fully supervised (weeks 1–4), tapering to levels of hybrid-supervised to self-managed exercise (weeks 5–48; 42% self-managed), and year 2 (48 wk) was mostly self-managed. Psychosocial support (monthly educational newsletters by e-mail) and behavioural support (text messages) were also provided. Message frequency increased gradually (from one to five times per week). Details on the intervention and modifications during coronavirus disease 2019 (COVID-19) are provided in the Supplementary material and the published study protocol [7].

### 2.4. Control

Control participants received psychosocial support via monthly educational newsletters. Self-directed unsupervised exercise was included in protocol version 4 to aid participant retention, with control participants dissatisfied if no exercise advice was provided while being asked to complete study questionnaires and attend testing visits. Print exercise recommendations were aligned with international clinical guidelines [15,16], to perform 150 min of moderate-intensity aerobic exercise and two structured resistance exercise sessions each week.

### 2.5. Year 1 assessments

Questionnaires were completed online via REDCap (or printed) prior to baseline and quarterly thereafter. Blood and urine collection and exercise testing were completed at baseline, 6 mo, and 12 mo. Exercise testing included CPET with ECG; 1-repetition maximum (1RM) tests including chest press, leg press, seated row, and leg extension (select tests excluded if contraindicated due to bone metastasis) [7,10,11]; 400-m walk test; anthropometry (weight, hip, and waist circumference); blood pressure; and heart rate.

### 2.6. Outcomes

Trial feasibility outcomes were specified post hoc after the study was closed because of poor accrual but use common standards. These include site activation (proportion of activated sites with randomised participants and reasons for not randomising patients), participant recruitment (proportion of men consented of those contacted, proportion of men randomised of those consented, and reasons for noneligibility or declining participation), process outcomes (proportion of participants completing each study assessment by time point and arm, and number of deaths, withdrawals, and withdrawal reasons during year 1 by arm), compliance outcomes (proportion of exercise sessions completed out of the total specified [$n$ = 144], proportion completed $\geq$70% of sessions [among those who completed year 1 and overall], and reasons for missed sessions), and adverse events. We counted once for each event per individual and used the event with the highest grade when there were multiple occurrences of the same event type. Session completion was also compared across mCRPC and mHSPC status. Changes in self-reported physical activity measured by the modified Godin-Shephard leisure time physical activity questionnaire [17], within and between arms, from baseline to cycle 12 are reported. Finally, factors influencing study feasibility are described. Efficacy analyses, including overall survival, physical fitness, and secondary biomarker and patient-reported outcomes, are ongoing and will be detailed in separate outcome papers.

### 2.7. Statistical analysis

Baseline characteristics were reported using mean with standard deviation or median with interquartile range (IQR), and $N$ (%) for categorical variables. Significant differences between arms were assessed using independent $t$ tests or Wilcoxon rank-sum tests [18]. Feasibility was

assessed using descriptive statistical methods for recruitment, completion of year 1 study activities (testing, specimen collections, and survey completion), partial or complete withdrawal, and exercise compliance for the exercise arm. Changes in self-reported exercise between groups were compared using an analysis of covariance while adjusting for the baseline assessment. Statistical significance was set at $p \leq 0.05$. All statistical analyses were performed using R version 4.4.3 (R Foundation for Statistical Computing, Vienna, Austria) [18]. For additional methods, please refer to the Supplementary material.

## 3. Results

### 3.1. Site activation

Twenty-one sites ($n$ = 21) were activated between 2016 and 2022 (Supplementary Table 2); 19 activated before and two after COVID-19 (March 2020). Of these, 13 (61.9%) randomised participants, with seven of the 13 (54%) sites randomising more than ten people. Reasons for no randomised participants at any site are presented in Supplementary Table 2. Among the 21 activated sites, nine had a physician principal investigator (PI; 44% randomised patients), and 12 had a nonclinical PI (75% randomised patients). However, most participants ($n$ = 131; 90%) were enrolled at sites with nonclinical PIs. The final protocol version permitted mHSPC and asynchronous remote exercise monitoring, though time between release (October 2019) and site-specific approval varied from 18 to 894 d (>2+ yr at UK sites), with five sites never activating prior to study closure.

### 3.2. Recruitment

From April 4, 2016 to February 27, 2023, 938 patients were approached, 226 (24%) were excluded based on the eligibility criteria, and 493 (53%) declined to participate, resulting in 232 (25%) consenting to the study and 145 being randomised (63% of those consented). The study was closed prior to reaching its accrual goal (last patient enrolled in 2023; see the Supplementary material) due to lower-than-expected recruitment. Most frequent barriers were travel ($n$ = 101) and time ($n$ = 77; Fig. 1).

### 3.3. Participant characteristics

The study's population ($n$ = 145; 27% mHSPC and 73% mCRPC) had a median age of 70 yr, median body mass index of 28.7 kg/m$^2$ and comprised individuals who were predominantly White (87%), university educated (67%), and married (76%; Table 1). The median time from diagnosis to enrolment was 3.7 yr. At baseline, the median self-reported exercise levels were as follows: 64 min of moderate- to vigorous-intensity aerobic exercise and 0 d of resistance exercise per week. The commonly reported comorbidities were the following: 52% hypertension, 57% elevated cholesterol, and 43% osteoarthritis or other joint or bone condition (Table 2). Antihypertensive, cholesterol-lowering, diabetes, bone, and opioid and nonopioid pain medications were used commonly (26–59%). Of those with mCRPC, 15% ($n$ = 21) were treatment naïve (no first-line mCRPC treatment); 43% ($n$ = 63) received androgen receptor pathway inhibitors (ARPIs) and were stable; 6% ($n$ = 8) had prostate-specific antigen progression; 3% ($n$ = 5) were treated with docetaxel as first-line therapy and were stable, while 6% ($n$ = 9) had progressed; and 27% ($n$ = 39) had mHSPC (Table 2). Of the participants, 99% were treated with luteinising hormone-releasing hormone analogue/antagonist treatments, 66% with ARPIs, 21% with steroids, 9% with antiandrogens, and 6% with chemotherapy at enrolment. Treatment and comorbidity data by protocol version are presented in Supplementary Table 3.

### 3.4. Process

Withdrawal and deaths are reported in Figure 1 and Supplementary Table 4. By 12 mo, seven participants (9%) had died and six (8%) withdrew in the intervention arm, while five (7%) had died and 12 (17%) withdrew in the control arm. Common withdrawal reasons included the following: study no longer worthwhile for patients ($n$ = 8), family burden ($n$ = 5), too ill ($n$ = 7), and assigned to the control arm ($n$ = 3). Twelve-month assessment completion rates were higher in the intervention arm (CPET: 64%, other exercise testing: 71%, surveys: 77%, specimens: 69%) than in the control arm (CPET: 51%, other exercise testing: 53%, surveys: 66%, specimens: 56%; Fig. 1).

### 3.5. Compliance and adverse events

Of the total enrolled population, the proportion of participants completing ≥70% of all 144 training sessions in year 1 was 69%, and the median exercise adherence for the 75 intervention arm participants was 84% (IQR:61%,95%), with no difference between mCRPC and mHSPC status ($p$ = 0.57). A heatmap of session status for each participant across year 1 is shown in Figure 2. Across the mCRPC and mHSPC groups, 34% and 38% of sessions were missed, respectively (Supplementary Table 5). The common reasons for missed sessions included study withdrawal and vacation, though other factors such as disease progression (mCRPC) or lack of interest (mHSPC) varied by group. At 12 mo, 58% of the intervention group and 24% of the control group met exercise guidelines (Supplementary Table 6). The 12-mo change in resistance exercise (0.3 d/wk) was significant, unlike the change in moderate- to vigorous-intensity physical activity (75.5 min/wk), when adjusting for baseline values (Supplementary Table 6). In the intervention and control arms, 162 and 109 adverse events were reported in year 1, respectively (Supplementary Table 7); only 19 adverse events were study related, and all of these occurred in the intervention arm.

### 3.6. Factors influencing global trial feasibility

Feasibility factors, collected ad hoc from site investigators, staff, and the steering committee, are presented in Table 3 with recommendations for future trials. The major obstacles included unrealistic timelines, high administrative burden to screen patients, and insufficient funding models. Other major roadblocks were logistical challenges such as conducting supervised exercise in congested cities, poor site-personnel partnerships, and the severe impact of the COVID-19 pandemic on recruitment.

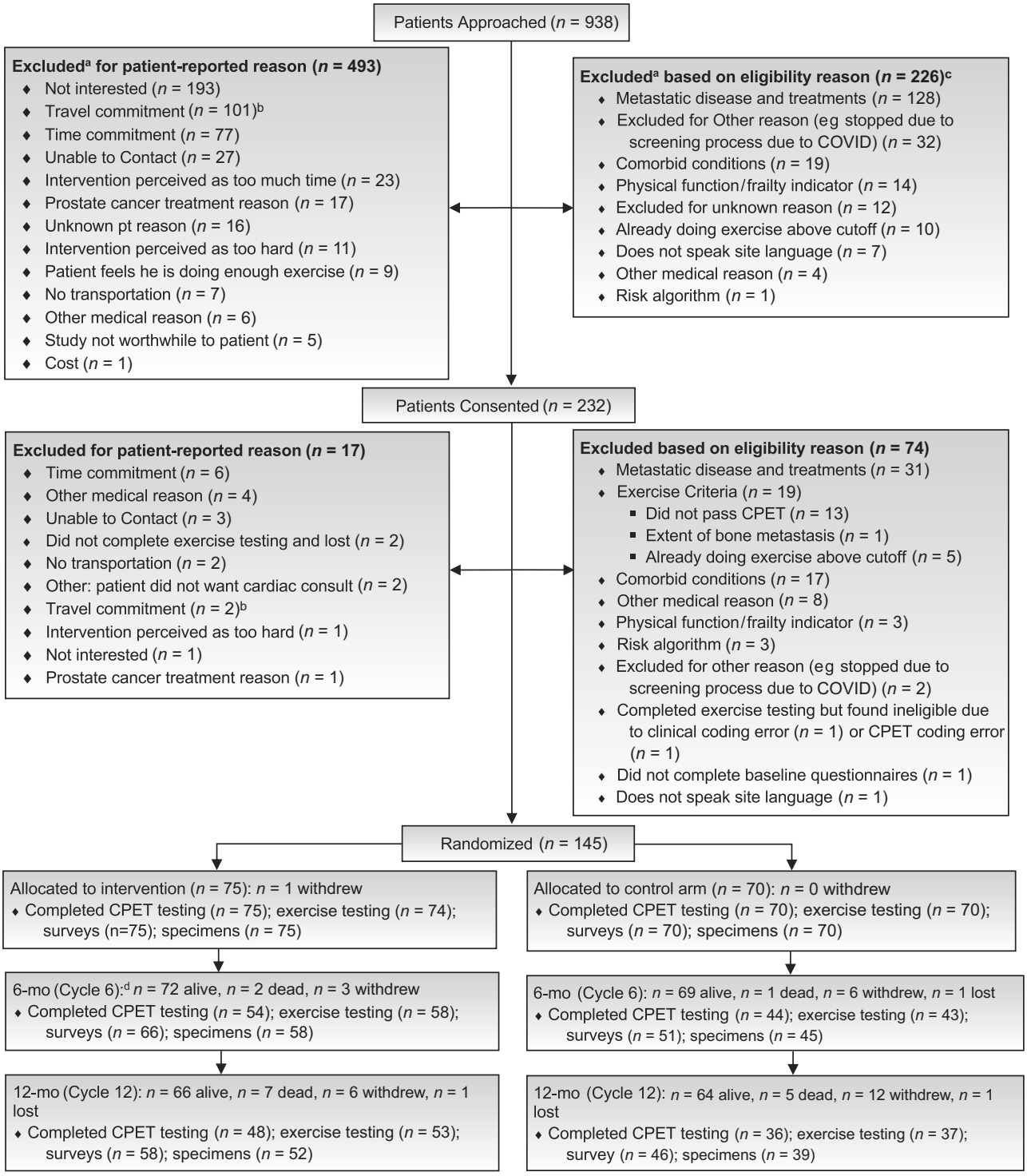


**Fig. 1 – Enrolment and follow-up in INTERVAL-GAP4. CPET = cardiopulmonary exercise test; COVID = coronavirus disease; INTERVAL-GAP4 = INTense ExeRcise for surviVAL-Global Action Plan 4; pt = patient. [a] Potential patients may have had one or more exclusion criteria noted. [b] This reason was part of the eligibility criteria. [c] One person gave two eligibility reasons. [d] Withdrawal can occur but does not necessarily mean that vital status is missing. Withdrawal status types are detailed in Supplementary Table 4.**

## 4. Discussion

INTERVAL-GAP4 represents the first trial that aimed to assess exercise and overall survival in PC; the second most common cancer. Recently, after 15 yr of recruitment, the first RCT was completed in colon cancer patients and reported longer disease-free and overall survival in the exercise versus the health-education groups (HR: 0.72; 95% CI: 0.55–0.94 and HR: 0.63; 95% CI: 0.43–0.94, respectively) [19]. Unfortunately, INTERVAL-GAP4 was closed

**Table 1 – Characteristics of INTERVAL-GAP4 participants (*N* = 145) [a]**

| Characteristics | Overall (*n* = 145) | Intervention (*n* = 75) | Control (*n* = 70) |
|---|---|---|---|
| *Demographics* | | | |
| Age (yr), median (IQR) [b] | 70 (64–74) | 70 (65–73) | 72 (64–77) |
| Race, *n* (%) | | | |
| White | 124 (87) | 66/74 (89) | 58/68 (85) |
| African/African American/Black/Black British/Caribbean | 3 (2) | 1/74 (1) | 2/68 (3) |
| Asian/Asian American/Asian British | 4 (3) | 2/74 (3) | 2/68 (3) |
| Middle Eastern | 1 (1) | 0/74 (0) | 1/68 (2) |
| Other | 10 (7) | 5/74 (7) | 5/68 (7) |
| Married or civil partnership, *n* (%) | 108 (76) | 55 (75) | 53 (77) |
| Education, *n* (%) | | | |
| Grade school or high school | 46 (33) | 24 (33) | 22 (32) |
| 2-yr college education or higher | 95 (67) | 48 (67) | 47 (68) |
| Currently employed, *n* (%) | 36 (25) | 19 (26) | 17 (25) |
| *Behavioural/lifestyle* | | | |
| Smoking status, *n* (%) | | | |
| Current smoker | 12 (8) | 6 (8) | 6 (9) |
| Past smoker | 67 (47) | 35 (48) | 32 (46) |
| Godin leisure-time exercise categories, *n* (%) | | | |
| Insufficiently active/sedentary | 61 (42) | 32 (43) | 29 (41) |
| Moderately active | 36 (25) | 20 (27) | 16 (23) |
| Active | 48 (33) | 23 (31) | 25 (36) |
| MVPA (min/wk), median (IQR) | 64 (0–180) | 60 (0–180) | 90 (0– 180) |
| Resistance exercise (times/wk), median (IQR) | 0 (0–1) | 0 (0–1) | 0 (0–1) |
| Meeting MVPA guidelines, *n* (%) [c] | 43 (30) | 22 (29) | 21 (30) |
| Meeting strength guidelines, *n* (%) [d] | 32 (22) | 18 (24) | 14 (20) |
| Meeting both exercise guidelines, *n* (%) | 16 (11) | 8 (11) | 8 (11) |
| Meeting neither exercise guideline, *n* (%) | 86 (59) | 43 (57) | 43 (61) |
| *Clinical* | | | |
| Time since diagnosis (yr), median (IQR) | 3.7 (1.5–7.9) | 4.7 (1.6–9.0) | 3.1 (1.5–7.8) |
| Stage, hormone sensitive, *n* (%) | 39 (27) | 21(28) | 18 (26) |
| Stage, castrate resistant, *n* (%) | 106 (73) | 54 (72) | 52 (74) |
| Halabi nomogram score | | | |
| Low | 74 (70) | 38 (70) | 36 (69) |
| Intermediate | 32 (30) | 16 (30) | 16 (31) |
| Gleason score at diagnosis, *n* (%) | | | |
| GG 1—Gleason ≤6 | 3 (2) | 0 (0) | 3 (4) |
| GG 2—Gleason 3 + 4 | 13 (9) | 4 (6) | 9 (12) |
| GG 3—Gleason 4 + 3 | 21 (15) | 10 (14) | 11 (15) |
| GG 4—Gleason 8 | 29 (20) | 16 (23) | 13 (17) |
| GG 5—Gleason ≥9 | 50 (35) | 27 (39) | 23 (31) |
| GG missing | 29 (20) | 13 (19) | 16 (21) |
| Laboratory levels at enrolment, median (IQR) | | | |
| PSA (ng/ml) | 0.8 (0.1–6.2) | 0.8 (0.1–4.9) | 0.9 (0.1–7.8) |
| Testosterone level (nmol/l) | 9.0 (5.8–14.4) | 12.0 (6.5–14.4) | 8.7 (5.8–14.4) |
| LDH | 187 (164–215) | 187 (164–223) | 188 (165–214) |
| Albumin * | 4.2 (3.9–4.4) | 4.3 (3.9–4.5) | 4.1 (3.9–4.3) |
| Haemoglobin * | 13.3 (12.6–14.0) | 13.2 (12.4–14.1) | 13.4 (12.8–13.9) |
| Metastasis, *n* (%) | | | |
| Bone | 121 (83) | 63 (84) | 58 (83) |
| Lymph nodes | 29 (20) | 11 (15) | 9 (13) |
| Visceral (lung, liver, bladder) | 2 (1) | 0 (0) | 2 (3) |
| Other | 2 (1) | 1 (1) | 1 (1) |
| Performance status, *n* (%) | | | |
| ECOG 0 | 104 (72) | 54 (72) | 50 (71) |
| ECOG 1 | 41 (28) | 21 (28) | 20 (29) |
| *Body composition* | | | |
| BMI (kg/m$^2$), median (IQR) | 28.7 (25.6–31.5) | 28.9 (25.9–31.4) | 28.7 (25.5–31.9) |
| BMI, categories | | | |
| Normal weight (<25.0 kg/m$^2$) | 27 (19) | 12 (16) | 15 (21) |
| Overweight (25.0–<30.0 kg/m$^2$) | 65 (45) | 35 (47) | 30 (43) |
| Obese (≥30.0 kg/m$^2$) | 53 (37) | 23 (37) | 15 (21) |
| Waist circumference (cm), median (IQR) | 102.5 (95.0–110.9) | 103.3 (96.2–110.5) | 102.3 (93.9–111.0) |
| Hip circumference (cm), median (IQR) | 102.9 (97.4–109.1) | 102.2 (97.1–106.9) | 103.6 (98.5–111.0) |
| Waist-to-hip ratio, mean (SD) | 0.99 (0.07) | 1.00 (0.07) | 0.98 (0.07) |

BMI = body mass index; ECOG = Eastern Cooperative Oncology Group; GG = grade group; INTERVAL-GAP4 = INTense ExeRcise for surviVAL-Global Action Plan 4; IQR = interquartile range; LDH = lactate dehydrogenase; MVPA = moderate to vigorous physical activity; PSA = prostate-specific antigen; SD = standard deviation.

[a] Missing data included race (*n* = 3, one intervention and two control), marital and smoking status (*n* = 3, two intervention and one control), education (*n* = 4, three intervention and one control), and employment status (*n* = 2, one intervention and one control).

[b] Age range is 44–89 yr overall, 44–89 yr for the intervention arm, and 51–88 yr for the control arm.

[c] Performing 150 min of moderate to vigorous exercise (all examples provided were aerobic activities; vigorous activity minutes was multiplied by 2).

[d] Resistance exercise (weight or strength training) for 2 d/wk.

**Table 2 – Health conditions and treatment characteristics of INTERVAL-GAP4 participants at study entry: p**re-existing conditions and medications, and prostate cancer treatments

| Characteristics | Overall (*N* = 145) | Intervention (*N* = 75) | Control (*N* = 70) |
|---|---|---|---|
| *Pre-existing conditions and medications* | | | |
| Pre-existing conditions, *n* (%) | | | |
| Hypertension/high blood pressure | 75 (52) | 43 (57) | 32 (46) |
| Elevated triglycerides | 22 (15) | 15 (20) | 7 (10) |
| Elevated cholesterol | 83 (57) | 45 (60) | 38 (54) |
| Type II diabetes | 24 (17) | 17 (23) | 7 (10) |
| Coronary artery disease | 14 (10) | 6 (8) | 8 (11) |
| Stroke or myocardial infarction | 9 (6) | 5 (7) | 4 (6) |
| Osteoarthritis or other joint or bone condition | 63 (43) | 32 (43) | 31 (44) |
| Concomitant medications, *n* (%) | | | |
| Antihypertensives | 86 (59) | 51 (68) | 35 (50) |
| Cholesterol lowering | 66 (46) | 40 (53) | 26 (37) |
| Other heart medication | 5 (3) | 3 (4) | 2 (3) |
| Diabetes | 43 (30) | 23 (31) | 20 (29) |
| Bone (bisphosphonates or denosumab) | 45 (31) | 22 (29) | 23 (33) |
| Pain medication (nonopioid) | 63 (43) | 32 (46) | 31 (41) |
| Opioid analgesics | 38 (26) | 17 (23) | 21 (30) |
| *Prostate cancer treatments* | | | |
| Previous treatments, *n* (%) | | | |
| Radical prostatectomy | 39 (27) | 21 (28) | 18 (26) |
| Radiotherapy | 59 (41) | 29 (41) | 30 (40) |
| Study treatment categories for advanced prostate cancer, *n* (%) [a] | | | |
| Category 1 (V2): mCRPC: treatment-naïve | 21 (15) | 9 (12) | 12 (17) |
| Category 2 (V2): mCRPC: receiving androgen receptor pathway inhibitor | 63 (43) | 33 (44) | 30 (43) |
| Category 3 (V4): mCRPC: PSA progression on androgen receptor pathway inhibitor | 8 (6) | 4 (6) | 4 (5) |
| Category 4 (V4): mCRPC: receiving chemotherapy | 5 (3) | 1 (1) | 4 (5) |
| Category 5 (V4): mCRPC: progressed following chemotherapy and receiving androgen receptor pathway inhibitor | 9 (6) | 5 (7) | 4 (5) |
| Category 6 (V5): mHSPC: high risk | 11 (8) | 6 (8) | 5 (7) |
| Category 7 (V5): mHSPC: high volume | 11 (8) | 7 (9) | 4 (6) |
| Category 8 (V5): mHSPC: high risk and high volume | 17 (12) | 9 (13) | 8 (11) |
| Treatments for advanced prostate cancer, *n* (%) | | | |
| LHRH analogue/antagonist | 144 (99) | 75 (100) | 69 (99) |
| First-generation antiandrogens (bicalutamide, flutamide, nilutamide, cyproterone acetate) | 13 (9) | 9 (12) | 4 (6) |
| Androgen receptor pathway inhibitor (abiraterone, enzalutamide, apalutamide, darolutamide) | 95 (66) | 47 (63) | 48 (69) |
| Taxane-based chemotherapy (docetaxel, cabazitaxel) | 9 (6) | 6 (8) | 3 (4) |
| Other life-prolonging agents (eg, PARPi, olaparib, and radium) | 2 (1) | 0 (0) | 2 (3) |
| Other agents of unknown effectiveness (ipilimumab, PD-1, siplucel-T, other immunotherapy; mitoxantrone, other chemotherapy) | 1 (1) | 0 (0) | 1 (1) |
| Radiation (to a metastatic site) | 2 (1) | 1 (1) | 1 (1) |
| Steroids (eg, prednisone/prednisolone) | 30 (21) | 14 (19) | 16 (23) |

INTERVAL-GAP4 = INTense ExeRcise for surviVAL-Global Action Plan 4; LHRH = luteinising hormone-releasing hormone; mCRPC = metastatic castrate-resistant prostate cancer; mHSPC = metastatic hormone-sensitive prostate cancer; PARPi = poly (ADP-ribose) polymerase inhibitor; PD-1 = programmed cell death protein 1; PSA = prostate-specific antigen; V2 = protocol version 2; V3 = protocol version 3; V4 = protocol version 4; V5 = protocol version 5; mCRPC = metastatic castrate-resistant prostate cancer.

[a] Categories 1–2 were available from September 23, 2015 (for pilot site under V2) and July 21, 2016 (for all sites under V3); categories 3–5 were available from April 23, 2018 (under V4); and categories 6–8 were available from October 4, 2019 (under V5).

after 7 yr of enrolment following a research advisory committee recommendation and an independent statistical review. Despite a revised proposal by the investigator team and facilitated by an author (S.M., at Movember Institute of Men's Health) following the pandemic—which included potential surrogate endpoints, a reduced sample size, and adjusted recruitment projections (and timeline) the plan was deemed unsatisfactory after considering other factors affecting feasibility (Table 3). In comparison with the planned 5-yr recruitment and >20 activated sites for INTERVAL-GAP4 to enrol 866 patients, the CHALLENGE trial had a planned 3-yr recruitment of 962 patients but ultimately required 15 yr and 55 trial sites (mostly in Canada and Australia) to enrol 889 patients [19]. We note the major differences between GAP4 and CHALLENGE. The GAP4 patient population consisted of patients with metastatic PC as a more advanced, frail population versus CHALLENGE that enrolled patients with stage II–III colon cancer. The intervention duration and intensity varied, whereby GAP4 prescribed 2 yr of three sessions per week of periodised aerobic and resistance exercise, which included moderate- and high-intensity workouts, while CHALLENGE prescribed 3 yr of at least moderate-intensity aerobic exercise, with the aim to increase it by at least ten metabolic equivalent task units (equivalent to 2.5 h of brisk walking) from baseline to 6 mo that was sustained or increased during the final 2.5 yr. Both used variations of a hybrid-supervised/self-managed exercise model, although GAP4 included more individualisation and supervision of exercise than CHALLENGE because of the high bone metastasis load compared with CHALLENGE.

Lessons from the global INTERVAL-GAP4 trial offer key feasibility insights for future exercise-oncology studies.

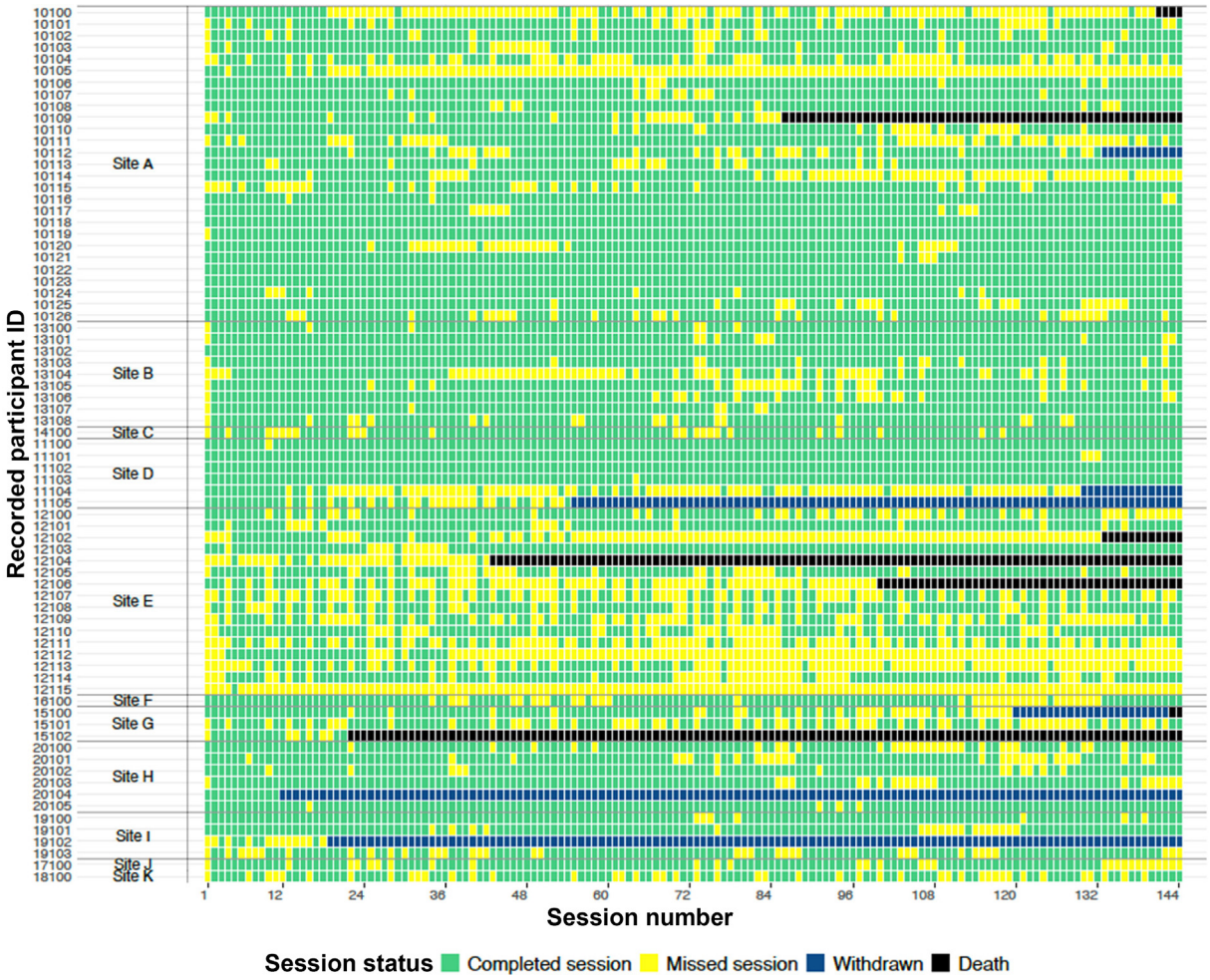


**Fig. 2 – Heatmap of exercise session status in year 1 by participant in the intervention arm (*N* = 75).**

Firstly, conducted before global exercise guidelines existed (published 6 yr after the first person enrolled) [14] and with only pilot data confirming safety for men with advanced PC (with other small studies confirming this over time) [10,11,13,20], few sites had the necessary experience with patients who have bone metastases. This inexperience limited the number of interested participating sites.

Secondly, the initial 1-yr goal to activate 20 trial sites was unrealistic, as it ultimately took 5 yr for 21 sites. Over 6.8 yr, this effort randomised only 145 participants, with just 62% of activated sites contributing to recruitment. Contract and start-up delays stemmed from many sites' inexperience with cancer exercise trials involving metastatic patients. Leveraging established networks (SWOG, Canadian Cancer Trials Group, etc.) could have streamlined activation and contracting.

Thirdly, a key barrier was a high administrative workload including a lengthy and resource-intensive screening process (see Supplementary Table 1 for the full screening criteria). Requirements such as laboratory work and CPET were particularly burdensome and should be re-evaluated for future study designs. These study processes were compounded by difficulties in integrating distinct departments (eg, exercise physiology and medical oncology), who often had no history of collaboration, shared infrastructure, or staffing. At some sites, the per-patient/per-activity payment model created barriers to site launch and enrolment, that is, sites did not have infrastructure or staff in place, the activity-based funding model was not sufficient to hire new personnel at 100% effort, and sites did not have financial economies of scale at their institutions to buffer this through other exercise trials or central organisational support. We also observed, however, that select sites that received further funds upfront still had recruitment challenges. Further, a lack of patient incentives and limited funding for investigator time impeded engagement and trial prioritisation at some centres. We suggest that for exercise trials, leadership from an exercise science expert with strong, pre-existing clinical collaborations and trial referral processes may be a more successful model than leadership from a clinician who needs to build exercise collaborations de novo, which requires time and substantial engagement.

Fourthly, recruitment was challenged by geographic location (eg, heavy traffic posed transportation challenges for Cedars-Sinai Medical Center in Los Angeles, CA, USA) and logistical barriers, such as expensive CPET testing during screening, which was a prestudy intense exercise safety measure, and a significant disruption from the COVID-19

**Table 3 – Factors influencing the global feasibility of the INTERVAL-GAP4 trial [a]**

| | Recommendations |
|---|---|
| *Trial factors* | |
| 1. Unrealistic site-activation timelines (to open 20 trial sites in the 1st year) | 1. 1a and 2a. Set realistic trial expectations and timelines upfront |
| 2. Overly ambitious recruitment rate (173 participants per year over 5 yr) | 2. 1a and 2a. Allow a longer recruitment period with contingency funding if recruitment duration must be extended |
| 3. High administrative workload to run the study (including lengthy screening processes) | 3. 3a. Simplify study design to collect only what is essential |
| 4. In-person supervision exercise delivery model created travel and logistical challenges for some sites | 4. 3a. Stricter consideration of necessary eligibility criteria and screening processes |
| 5. Clinician-participant apprehension about exercise safety in advanced prostate cancer | 5. 4a. Offer various models of exercise delivery upfront |
| 6. Control arm participants unable to be blinded to exercise, challenging retention, requiring the explained importance of equipoise | 6. 5a. and 6a. Improve health messaging to help people understand the potential benefit of exercise in this population and the important of equipoise in all randomised trials, and accommodate exercise modifications based on individual needs |
| 7. Many patients approached were not interested in participation, and study assessment completion rates varied by group | 7. 6a and 7a. Consider participant incentives |
| *Site factors* | |
| 1. Inexperienced trial sites with no pre-existing links between clinical and exercise oncology | 1. 1a. Ensure that trial sites have established relationships and partnerships, efficient pathways to identify people with advanced cancer |
| 2. Inexperienced trial sites with no pre-existing infrastructure for a clinical exercise trial | 2. 2a. Ensure that trial sites have appropriate trial-specific and exercise delivery infrastructure. |
| 3. Identified sites were insufficient in number, and unmet feasibility metrics posed a risk to recruitment goals | 3. 1a and 2a. Fund activities for on-the-ground support and monitoring to ensure sites are adequately equipped and trained (staff, systems, resources) |
| 4. Differences in site structures (clinician vs nonclinician site principal investigators) | 4. 1a and 4a. Ensure that sites have and maintain long-term collaborations with clinical partners for collection of clinical endpoint data, especially for studies with repeated collection of long-term clinical endpoints |
| 5. Differences in how investigators are funded across countries | 5. 3a. Ample activated sites are critical to reach recruitment goals, which requires more sites to be involved while having strict site feasibility evaluations |
| 6. Competition between therapeutic and exercise trials in advanced prostate cancer at some trial sites adversely impacted GAP4 recruitment | 6. 5a. Consider providing sustained investigator support with consideration of country-specific investigator funding models |
| | 7. 6a. Strengthen trial visibility and adopt other strategies to elevate exercise trials along with therapeutic trials at the site level |
| *External factors* | |
| 1. COVID-19 pandemic | 1. 1a. Prepare in advance for worse-case scenarios and have contingency plans to pivot, if needed, in a timely manner |
| 2. Contractual delays between the funder and trial sites | 2. 2a. Plan for contract, ethics, and governance delays. Utilise pre-existing clinical trial networks to streamline site activation and contract |
| 3. Limited forward funding and lean per-patient budget. Budget included an upfront payment and per-patient payment model, and assumption of having prior infrastructure/resources in place, including staff | 3. 2a, 3a, 4a, and 5a. Appropriately budget and fund activities that includes a budget contingency plan for delays or trial extension, accounts for cost inflation, and supports varied cost models to forward fund trial activities based on site context |
| 4. Cost inflation of trial activities over time relative to fixed trial funding rates | |
| 5. Infrastructure support to extend the trial beyond the planned 5-yr recruitment period and minimum 3-yr patient follow-up was not available in the planned budget | |

COVID-19 = coronavirus disease 2019; INTERVAL-GAP4 = INTense ExeRcise for surviVAL-Global Action Plan 4.

[a] The table was developed by the Study Coordination Centre and Exercise Coordination Centre based on feedback received from site investigators, staff, and the steering committee. Each factor is linked to a recommendation (#1 in column 1 is linked to #1a in column 2).

pandemic. Many institutions paused their trial activities during this period, deprioritised nonessential research ethics reviews, and suspended nonessential research activities. This included pausing CPETs due to concerns of COVID-19 transmission, which halted enrolment.

Recruitment for this trial proved challenging, with only 15% of approached individuals being randomised (Fig. 1). The common reasons for nonparticipation included travel and time commitment, as well as perceptions about exercise intensity and limited personal benefit, while others refused to be randomised to the control group believing exercise was superior. To improve participation in future trials, researchers could provide alternative exercise options to the control group, more flexible intervention models, and more effective health messaging to address participant barriers. High compliance to exercise sessions suggests that the intervention was feasible in mCRPC and mHSPC patients, who varied by age, comorbidity burden, and advanced PC treatments. However, there was variation in programme compliance across sites (Fig. 2). Additionally, a total of 18 men (12%) withdrew, with withdrawals in the control arm (12 men) doubling those in the intervention arm (six men). This is comparable to two 3-mo exercise trials in people with metastatic PC reporting 82% and 86% completion rates (CHAMP trial [21] and another trial at the pilot site [11]). Survey completion was moderate; this may be due to a high survey burden in the INTERVAL-GAP4 trial in addition to deaths and withdrawals during the study period.

### 4.1. Strengths and limitations

Few exercise trials have been performed in this population, and none have evaluated overall survival. Smaller exercise studies among PC patients with bone metastases [13] demonstrate that supervised exercise preserves or improves physical function and muscle strength [11], remotely monitored exercise can yield high adherence [21,22], and other modes of delivery with home-based [23] and internet-based [24] exercise prescriptions are effective. More recently, this advanced cancer population have safely been

included in multicomponent care programmes [25,26]. INTERVAL-GAP4 importantly tested a longer, periodised, autoregulated, and intense exercise programme compared with other trials to date, and demonstrated high 1-yr adherence, despite some people withdrawing due to illness. This shows people are motivated to engage in health behaviour change, but need guidance, especially through health declines. Additionally, the study was conducted through the pandemic, adding evidence to flexible delivery of exercise, which may have contributed to the high adherence at 1 yr [27].

The study has several limitations. Firstly, while participants were enrolled at 13 sites across six different countries (Australia, Canada, USA, UK, Germany, and The Netherlands), four sites enrolled most (79%) participants, and 36% of participants came from one site. This suggests global feasibility, but the distribution of enrolment across sites may have disproportionately influenced some results. Secondly, generalisability of the findings may be limited, as participants in an exercise trial may be more compliant than a general patient population with metastatic cancer, and had to be relatively inactive (eligibility requirement of vigorous exercise $\leq$60 min/wk and structure resistance exercise $\leq$1 d/wk). Thirdly, as an unblinded trial, concealment was not possible, allowing for possible contamination of the trial. Lastly, due to approval delays and COVID-19, a fully remote programme was not implemented (protocol version 5) [21], though sites pivoted to tele-exercise. Although few remote programmes were attempted before COVID-19 [28], telehealth is now more widely accepted and has the potential to overcome barriers and promote patient engagement [29].

## 5. Conclusions

A supervised to self-managed, moderate- to high-intensity exercise programme for men with metastatic PC demonstrated high adherence and tolerability, and the programme proved resilient by transitioning effectively to telepractice during the COVID-19 pandemic. However, the study was closed to accrual early due to recruitment and operational challenges. Conducting multisite exercise trials of this scale is inherently complex and requires prioritising the study, strong clinician-exercise partnerships, and robust infrastructure. These findings indicate that future large-scale phase 3 trials examining exercise effects on disease outcomes will need careful planning, realistic timelines, adequate site numbers, and streamlined protocols. The limited participation in INTERVAL-GAP4 reflects the demands of a 2-yr survival trial—not routine clinical practice. Enrolment required randomisation, repeated CPETs, biological sampling, extensive questionnaires, and travel to specialised sites for supervised sessions—burdens that differ markedly from flexible clinical models. Thus, GAP4 recruitment challenges should not be interpreted as difficulty implementing exercise in practice. Recent guidelines now provide a framework for integrating exercise programming into clinical care for patients with bone metastases [14]. Building on the limitations identified in the GAP4 trial, further research is needed in implementation science to effectively deliver exercise-oncology programmes to patients with advanced cancer across diverse clinical and community settings.

***Author contributions*:** Stacey A. Kenfield had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

*Study concept and design*: Kenfield, Hart, Courneya, Greenwood, Chan, Zhang, Van Blarigan, Ryan, Galvão, Newton, Saad.
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*Analysis and interpretation of data*: Kenfield, Hart, Courneya, Greenwood, Chan, Sison, Zhang, Ung, Newton, Saad.
*Drafting of the manuscript*: Kenfield, Hart.
*Critical revision of the manuscript for important intellectual content*: All authors.
*Statistical analysis*: Kenfield, Hart, Greenwood, Zhang, Ung.
*Obtaining funding*: Newton, Saad.
*Administrative, technical, or material support*: Kenfield, Hart, Greenwood, Sison, McKeown, Newton, Saad.
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*Other*: None.

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## Appendix A. Supplementary data

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