

Supplementary material for:

Wearable-derived Physical Activity (PA) and Patient-reported Fatigue and Sleep Differ by Hot Flash (HF) Severity Levels During the Initial Treatment Phase (ITP) in the LIBERTAS Trial

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Supplemental Table 1: Baseline and disease characteristics

n (%) or Median (range)	Low HF severity ^a			High HF severity ^a		
	Overall (n=147)	ADT-naïve (n=49)	HF-emergent (n=52)	Overall (n=148)	ADT-naïve (n=56)	HF-emergent (n=54)
Age, y	71.0 (48-85)	72.0 (49-82)	72.0 (49-87)	70.0 (51-88)	69.5 (51-86)	72.0 (54-88)
<65	39 (26.5)	13 (26.5)	12 (23.1)	38 (25.7)	14 (25.0)	5 (9.3)
65-69	26 (17.7)	7 (14.3)	12 (23.1)	32 (21.6)	14 (25.0)	11 (20.4)
70-74	39 (26.5)	15 (30.6)	10 (19.2)	32 (21.6)	12 (21.4)	18 (33.3)
≥75	43 (29.3)	14 (28.6)	18 (34.6)	46 (31.1)	16 (28.6)	20 (37.0)
Race						
Asian	13 (8.8)	11 (22.4)	6 (11.5)	5 (3.4)	4 (7.1)	4 (7.4)
Black/African American	8 (5.4)	2 (4.1)	4 (7.7)	19 (12.8)	5 (8.9)	6 (11.1)
White	111 (75.5)	29 (59.2)	36 (69.2)	106 (71.6)	36 (64.3)	37 (68.5)
Other/Multiple/Unknown	15 (10.2)	7 (14.3)	6 (11.5)	18 (12.2)	11 (19.6)	7 (13.0)
Body mass index, kg/m ²	27.4 (18-43)	26.1 (22-41)	27.3 (22-44)	26.2 (20-39)	26.2 (20-39) ^b	25.5 (17-43)
Time from metastatic diagnosis to initial therapy, mos	2.20 (0.3-64.9)	1.48 (0.3-45.6)	1.94 (0.3-45.6)	2.56 (0.3-151.0)	2.09 (0.6-151.0)	1.89 (0.3-28.8)
Tumor stage at diagnosis						
T1-T2	60 (40.8)	20 (40.8)	23 (44.2)	59 (40.0)	20 (35.7)	22 (40.7)
T3-T4	77 (52.4)	23 (46.9)	26 (50.0)	71 (48.0)	32 (57.1)	30 (55.6)
TX/Missing	10 (6.8)	6 (12.2)	3 (5.8)	18 (12.2)	4 (7.1)	2 (3.7)
Lymph node stage at diagnosis						
N0	52 (35.4)	16 (32.7)	15 (28.8)	59 (39.9)	23 (41.1)	24 (44.4)
N1	67 (45.6)	23 (46.9)	24 (46.2)	56 (37.8)	18 (32.1)	19 (35.2)
NX	28 (19.0)	10 (20.4)	13 (25.0)	33 (22.3)	15 (26.8)	11 (20.4)
Baseline total testosterone, nmol/L	0.73 (0.1-25.6)	11.29 (0.1-25.6)	3.89 (0.1-24.4)	0.70 (0.0-1075.9 ^c)	11.83 (0.5-1075.9 ^c)	11.09 (0-1075.9 ^c)
≤0.7	71 (48.3)	5 (10.2)	19 (37.3)	75 (50.7)	4 (7.1)	11 (20.4)
>0.7	76 (51.7)	44 (89.8)	32 (62.7)	73 (49.3)	52 (92.9)	43 (79.6)
Eastern Cooperative Oncology Group performance status						
0	113 (76.9)	37 (75.5)	43 (82.7)	120 (81.1)	49 (87.5)	45 (83.3)
1	33 (22.4)	12 (24.5)	9 (17.3)	28 (18.9)	7 (12.5)	9 (16.7)
2	1 (0.7)	0	0	0	0	0
Gleason score at diagnosis						
≤7	49 (33.3)	17 (34.7)	16 (30.8)	55 (37.2)	18 (32.1)	23 (42.6)
>7	94 (63.9)	31 (63.3)	34 (65.4)	89 (60.1)	38 (67.9)	31 (57.4)
Missing	4 (2.7)	1 (2.0)	2 (3.8)	4 (2.7)	0	0
Baseline Prostate-specific antigen, µg/L	7.00 (0.0-2399.0)	24.50 (0.4-2399.0)	9.58 (0.1-2399.0)	7.11 (0.0-4433.0)	26.24 (0.4-4433.0)	24.40 (0.3-1589.0)
Tumor volume						
High ^d	74 (50.3)	30 (61.2)	25 (48.1)	66 (44.6)	24 (42.9)	22 (40.7)
Low ^e	73 (49.7)	19 (38.8)	27 (51.9)	82 (55.4)	32 (57.1)	32 (59.3)

^aThe average daily severity-adjusted HF score was derived by multiplying a numeric scalar corresponding to severity levels (mild-1, moderate-2, severe-3, and very severe-4) by the frequency of each of these scores. This total composite score was then averaged over all days where the participant had a HF severity assessment completed for that analysis visit. Low and high severity HF data shown here represent the 6-month score.

^bOut of n=55 participants with a BMI measurement available.

^cValues shown are as originally entered into electronic database. Baseline laboratory values are defined as the measurement closest in time to the first dose of study treatment (on or prior to the first dose). When multiple pre-treatment values are available, the value nearest the treatment start date is selected as baseline.

^dDefined as (1) visceral metastases or (2) at least 4 bone lesions, with at least 1 bone lesion outside of the vertebral column or pelvis.

^eDefined as any other metastases not meeting the definition of high-volume metastatic hormone-sensitive prostate cancer.

ADT, androgen-deprivation therapy; HF, hot flash.



Supplemental Table 2: Daily life activity behavior in the ITP overall population.

	Time	Low HF				High HF				p Wilcoxon
		N	Mean ± SD	Median	IQR	N	Mean ± SD	Median	IQR	
Awake sedentary time (min/d)										
	Baseline	131	444.62 ± 123.77	427.00	383.38-507.22	126	465.19 ± 96.72	466.99	403.71- 528.67	0.023
	Cycle 4 Day 1	135	435.38 ± 95.21	437.57	379.72-497.82	131	462.81 ± 124.50	460.78	406.64-523.61	0.029
	Cycle 7 Day 1	142	432.66 ± 116.33	427.98	373.77-486.08	141	455.85 ± 121.27	465.12	386.35- 516.71	0.012
Awake MVPA time (%)										
	Baseline	131	11.43 ± 6.27	10.69	7.23-14.71	126	9.72 ± 3.72	9.10	7.44-11.34	0.035
	Cycle 4 Day 1	135	11.92 ± 7.55	9.94	7.53-14.65	131	9.77 ± 3.57	9.36	7.48-11.64	0.068
	Cycle 7 Day 1	142	10.97 ± 6.70	10.00	6.79-13.71	141	9.37 ± 3.91	9.39	6.60-11.41	0.047

HF, hot flash; IQR, interquartile range; ITP, initial treatment phase; MVPA, moderate-to-vigorous physical activity; SD, standard deviation.



Supplemental Table 3: Daily life activity behavior in the ITP ADT-naïve subgroup.

	Time	Low HF				High HF				p Wilcoxon
		N	Mean ± SD	Median	IQR	N	Mean ± SD	Median	IQR	
Awake sedentary time (min/d)										
	Baseline	43	437.16 ± 89.81	413.12	384.86-482.53	47	483.62 ± 102.49	486.54	412.00-563.65	0.014
	Cycle 4 Day 1	44	427.20 ± 88.16	430.46	373.80-484.35	49	469.01 ± 87.40	486.78	406.65-536.12	0.022
	Cycle 7 Day 1	47	414.65 ± 88.64	411.72	360.82-462.70	53	469.34 ± 105.48	474.02	405.07-532.25	0.005
Awake MVPA time (%)										
	Baseline	43	13.14 ± 8.29	11.40	8.44-16.27	47	9.68 ± 3.58	9.17	7.06-11.29	0.015
	Cycle 4 Day 1	44	12.66 ± 7.00	11.83	8.07-16.66	49	9.86 ± 2.98	9.91	8.06-10.96	0.050
	Cycle 7 Day 1	47	12.93 ± 9.40	11.26	8.36-16.35	53	9.64 ± 3.50	9.11	7.39-11.34	0.025

ADT, androgen-deprivation therapy; HF, hot flash; IQR, interquartile range; ITP, initial treatment phase; MVPA, moderate-to-vigorous physical activity; SD, standard deviation.



Supplemental Table 4: Daily life activity behavior in the ITP HF-emergent subgroup.

	Time	Low HF				High HF				p Wilcoxon
		N	Mean ± SD	Median	IQR	N	Mean ± SD	Median	IQR	
Awake sedentary time (min/d)										
	Baseline	46	417.70 ± 88.91	412.74	369.53-466.77	48	464.73 ± 90.17	465.44	397.73- 531.49	0.011
	Cycle 4 Day 1	47	439.52 ± 122.90	441.83	375.80-490.84	45	462.06 ± 80.59	480.21	399.48-526.93	0.096
	Cycle 7 Day 1	50	416.44 ± 109.31	401.52	366.68-468.44	50	455.90 ± 83.73	471.05	390.38-519.47	0.013
Awake MVPA time (%)										
	Baseline	46	11.91 ± 5.56	10.48	7.16-15.80	48	10.45 ± 4.06	9.55	7.43-12.27	0.234
	Cycle 4 Day 1	47	12.82 ± 9.74	9.94	7.31-17.38	45	10.10 ± 3.43	9.17	7.76-11.43	0.430
	Cycle 7 Day 1	50	10.39 ± 5.48	9.30	6.46-14.50	50	9.41 ± 3.37	8.57	7.12-10.90	0.657

HF, hot flash; IQR, interquartile range; ITP, initial treatment phase; MVPA, moderate-to-vigorous physical activity; SD, standard deviation.



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