

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

A.K. Morgans,¹ A. Azad,² M.A. Badillo Santoyo,³ D.E. Rathkopf,⁴ K. Runcie,⁵ G. Gotto,⁶ A.S. Merseburger,⁷ A. Dos Santos,⁸ R.Z.U. Rehman,⁹ S. Shopeju,⁸ M. Chatterjee,¹⁰ J. Li,¹¹ D. Sanchez,¹² A. Bhaumik,¹³ S. Todd,¹⁴ V. Thirugnanam,¹⁵ Y. Huo,¹⁰ S. Mundle,⁸ M. Wildgust,⁸ N. Agarwal¹⁶

¹Medical Oncology Department, Dana-Farber Cancer Institute, Boston, MA, USA, ²Department of Medical Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia, ³Department of Urology, Hospital Aranda de la Parra, Leon, Mexico, ⁴Medicine Department, MSKCC - Memorial Sloan Kettering Cancer Center, New York, NY, USA, ⁵Oncology Department, HICCC - Herbert Irving Comprehensive Cancer Center - Columbia University, New York, NY, USA, ⁶Department of Oncology, University of Calgary, Southern Alberta Institute of Urology, Calgary, Canada, ⁷Urologie, UKSH - Universitätsklinikum Schleswig-Holstein - Campus Lübeck, Lübeck, Germany, ⁸Global Medical Affairs Oncology, Johnson & Johnson, Raritan, NJ, USA, ⁹Data Science, Johnson & Johnson, High Wycombe, UK, ¹⁰Data Sciences, Johnson & Johnson, Cambridge, MA, USA, ¹¹Data Sciences, Johnson & Johnson, Neuss, Germany, ¹²Oncology Data Science & Digital Health, Johnson & Johnson, Raritan, NJ, USA, ¹³Biostatistics, Johnson & Johnson, Titusville, NJ, USA, ¹⁴Data Analysis, Johnson & Johnson, London, UK, ¹⁵Data Sciences, Johnson & Johnson, Santa Clara, CA, USA, ¹⁶Hematology-Oncology Department, University of Utah - Huntsman Cancer Institute, Salt Lake City, UT, USA

Key Takeaway



During the ITP of LIBERTAS, participants with more severe HF at month 6 reported greater sleep disturbance and fatigue, along with lower levels of PA

Conclusions



Participants who went on to report more severe HF at 6 months were already more sedentary at baseline and remained so throughout the ITP



Continuous PA measures corroborated patient-reported outcomes, with high HF severity being associated with a lower MVPA and greater fatigue and sleep disturbance



These findings highlight the value of continuous monitoring of PA with wearable digital health technologies to objectively characterize patient wellbeing during prostate cancer therapy together with traditional patient-reported outcomes



Please scan QR code

Poster

Supplementary material

<https://www.congresshub.com/Oncology/ESMO2026/Apalutamide/Morgans>

Copies of this poster obtained through QR, AR and/or text key codes are for personal use only and may not be reproduced without written permission of the authors.

Disclosures

A.K.M. reports consulting for Astellas, AstraZeneca, Bayer, Bristol Myers Squibb, Curium, Exelixis, Exact Sciences, Johnson & Johnson, Lantheus, MacroGenics, Merck, Novartis, Pfizer, Sumitomo Pharma, Inc, Telix, and Tolmar; and research for Astellas, Bayer, Johnson & Johnson, Lantheus, Pfizer, Sumitomo Pharma, Inc, and Telix.

Introduction

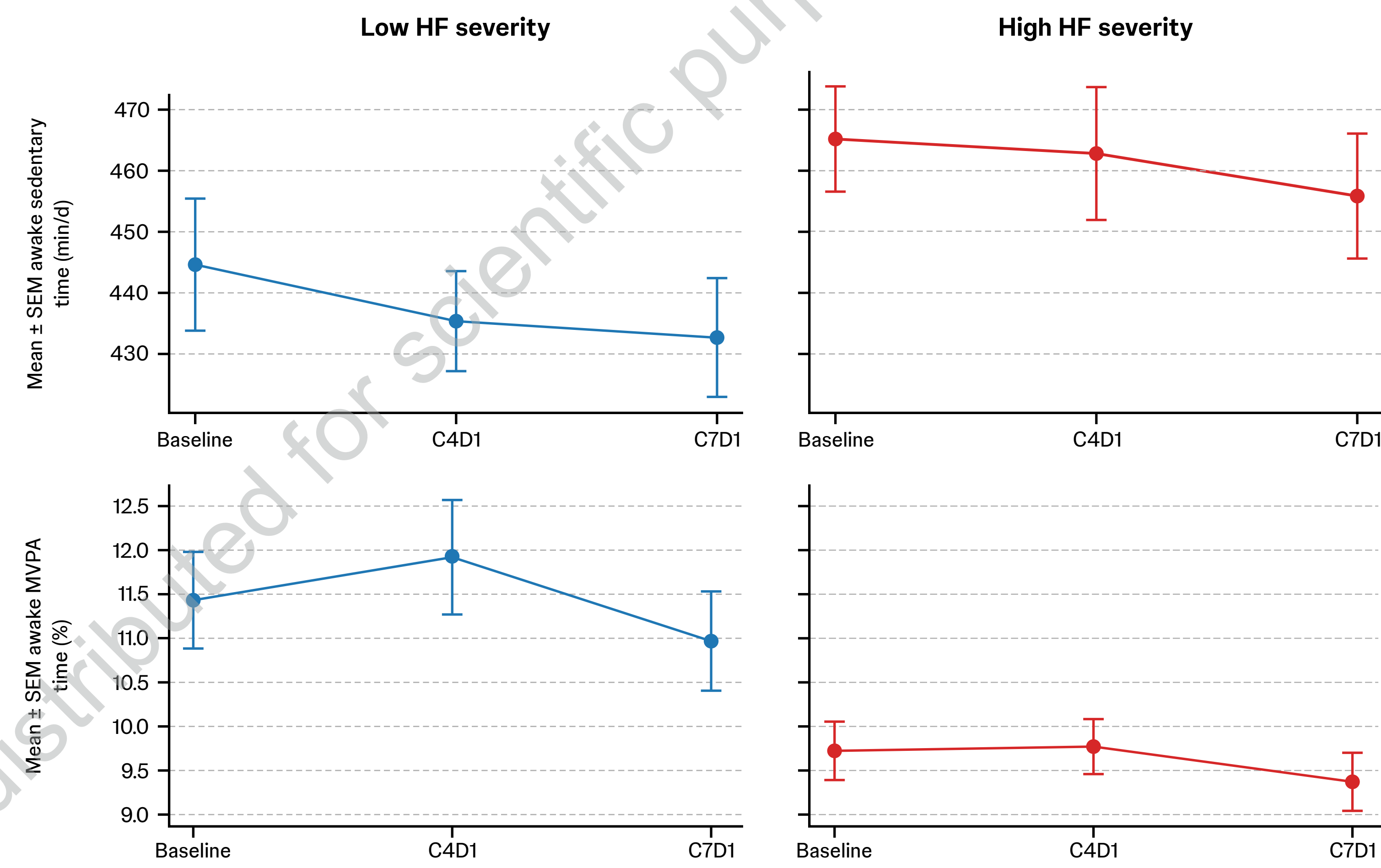
- Prolonged androgen deprivation therapy (ADT) for metastatic castration-sensitive prostate cancer (mCSPC) is associated with adverse musculoskeletal, sexual, mental, and cardiovascular health effects^{1,2}
 - Apalutamide (APA) is an androgen receptor inhibitor approved with ADT for mCSPC
- LIBERTAS (NCT05884398) is a phase 3 trial evaluating intermittent versus continuous ADT following a 6-month ITP of APA+ADT in newly diagnosed mCSPC
- HF are burdensome ADT-related toxicities associated with poorer sleep, lower energy levels, and impaired daily functioning
- Using ITP data, we explored associations between HF severity and wearable-derived PA and patient-reported fatigue and sleep symptoms

Results

Participants

- Of 420 participants who enrolled in the ITP, 295 experienced a HF at C7 (overall population; HF severity: low, n=147; high, n=148)
 - 105 participants were included in the ADT-naïve subgroup (HF severity: low, n=49; high, n=56)
 - 106 participants were included in the HF-emergent subgroup (HF severity: low, n=52; high, n=54)
- Across groups and HF severities, participant median age was between 69.5 and 72.0 years, and median BMI was 25.5–27.4 kg/m². The majority of participants had an ECOG PS of 0, baseline total testosterone >0.7 nmol/L, and Gleason score >7 (**Supplemental Table 1**)
- Daily life activity behavior**
 - Daily wear compliance was high across visits and groups (overall population; mean [SD]: 95.10% [9.90%] to 96.05% [9.14%])
 - Across populations, participants with high HF severity spent more time sedentary while awake than those with low HF severity at most time points (p<0.05, **Figures 2-4**)
 - Differences in median sedentary awake time between HF severity groups were present at baseline and persisted through C7D1 (overall population, p<0.05)
 - Participants with high HF severity also had lower awake MVPA in the overall population (p<0.05, **Figure 2**) and the ADT-naïve subgroup (p<0.05, **Figure 3**); a similar trend was seen in the HF-emergent subgroup (p>0.05, **Figure 4**)

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

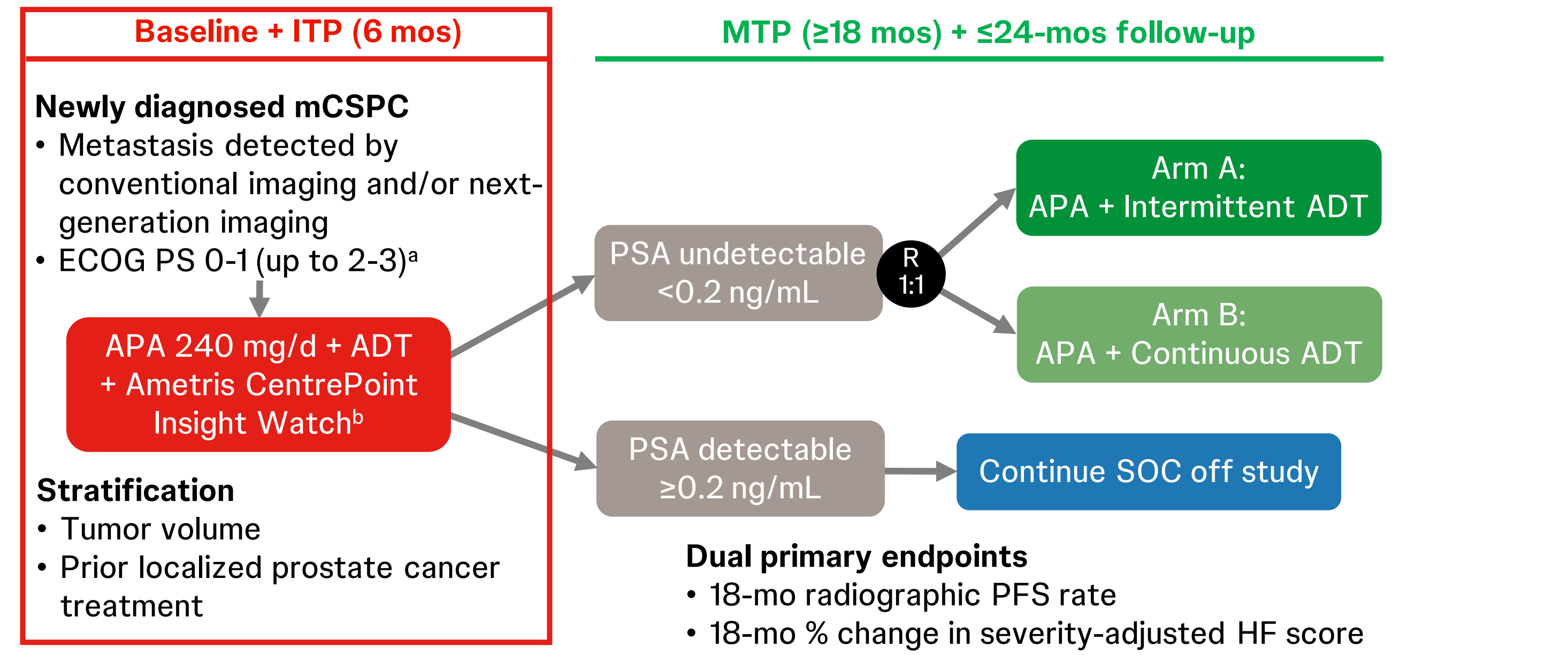


Corresponding tabular data shown in Supplemental Table 2. SEM, standard error of the mean.

Methods

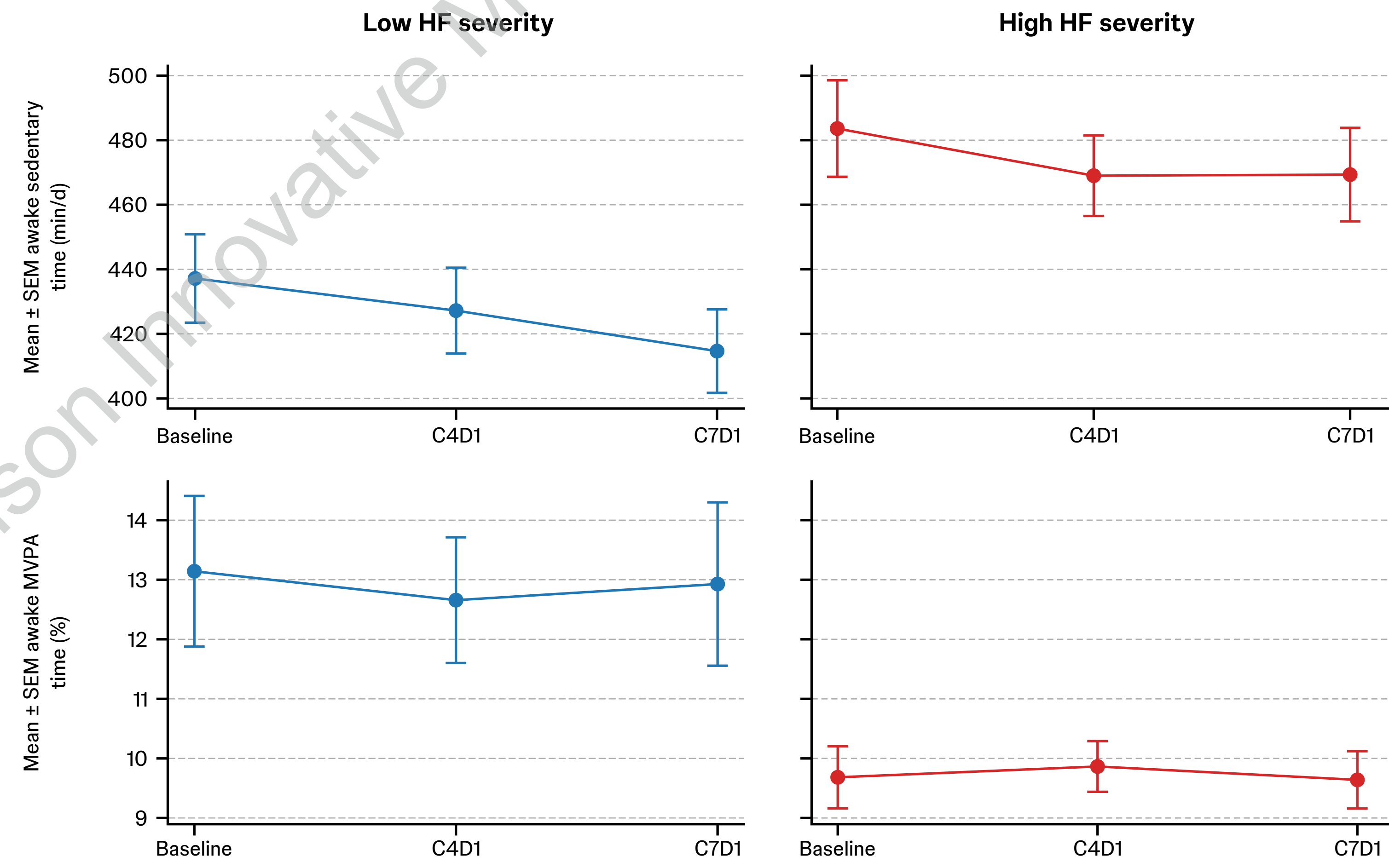
- During the ITP, PA was continuously assessed with a wrist-worn device (**Figure 1**)
- Among participants who experienced HF during the ITP, HF severity was classified as low/high based on median average daily severity-adjusted HF score at 6 mos
 - ADT-naïve subgroup:** no prior ADT for mCSPC (medical/surgical castration)
 - HF-emergent subgroup:** no HF at baseline with HF reported during ITP
- PA measures included daily sedentary time and daily time spent in moderate-to-vigorous PA (MVPA)³
- Fatigue and sleep disturbance were characterized using corresponding single items of the Patient Health Questionnaire (PHQ)-9,^{4,5} administered at baseline and Day (D) 1 of Cycles (C) 4 and 7
- Analyses were exploratory with no adjustment for multiplicity

Figure 1: LIBERTAS Study Design



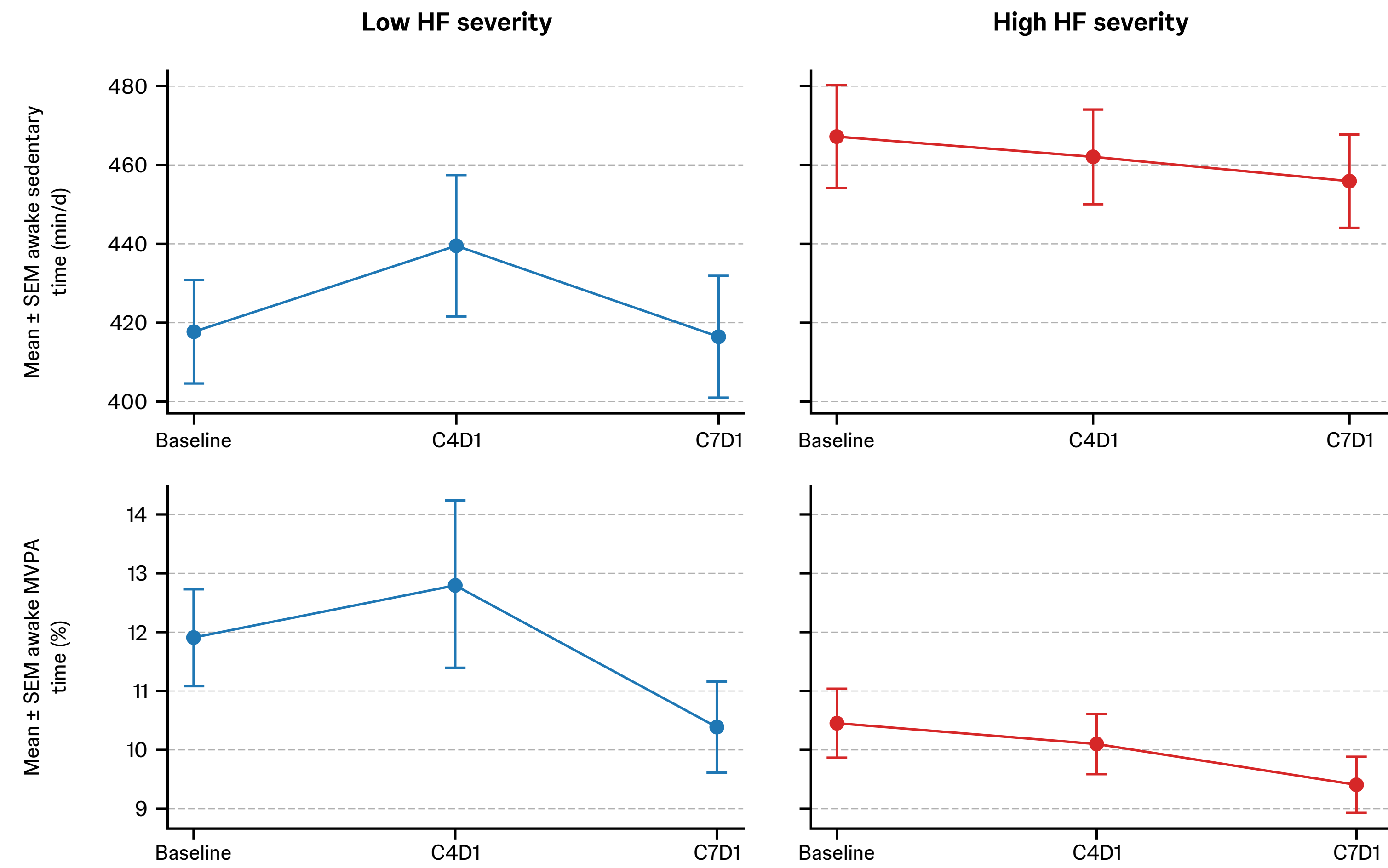
ECOG PS, Eastern Cooperative Oncology Group performance status; MTP, main treatment phase; PFS, progression-free survival; PSA, prostate specific antigen; R, randomized; SOC, standard of care. *Eligible if score related to stable physical limitations and not PC or associated therapy. *A valid day was defined as ≥10 h of wear while awake or ≥16 h over a full day.

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



Corresponding tabular data shown in Supplemental Table 3. SEM, standard error of the mean.

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

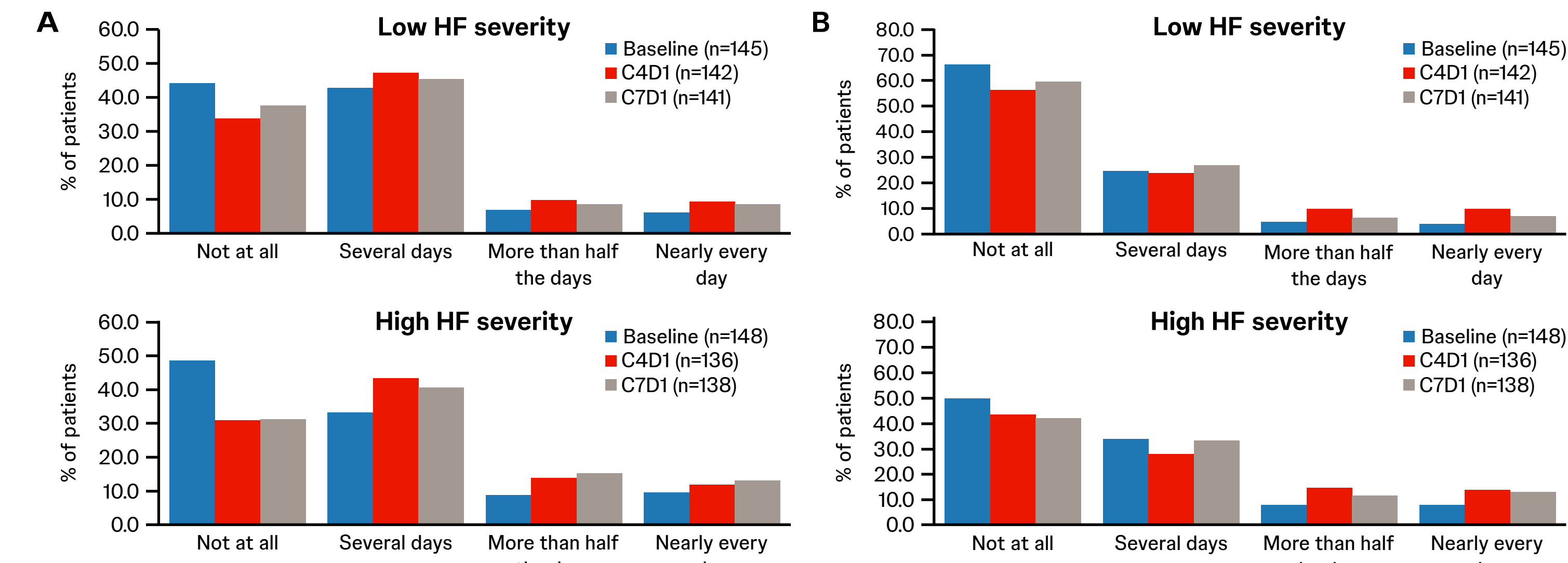


Corresponding tabular data shown in Supplemental Table 4. SEM, standard error of the mean.

Fatigue and sleep disturbance

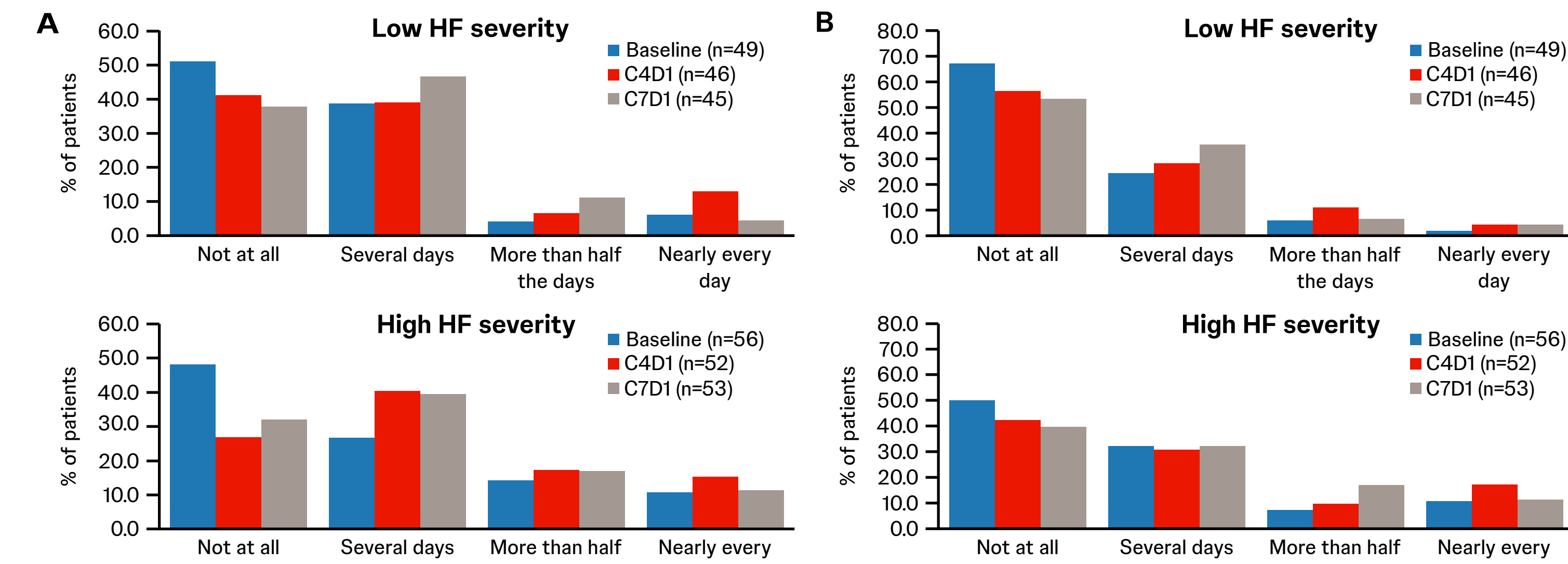
- There was a numerically higher proportion of high HF severity participant-reported fatigue and sleep disturbance after 6 months in all ITP populations assessed (**Figures 5-7**)

Figure 5: Patient-reported PHQ-9 fatigue (A) and sleep disturbance (B) in the ITP overall population.



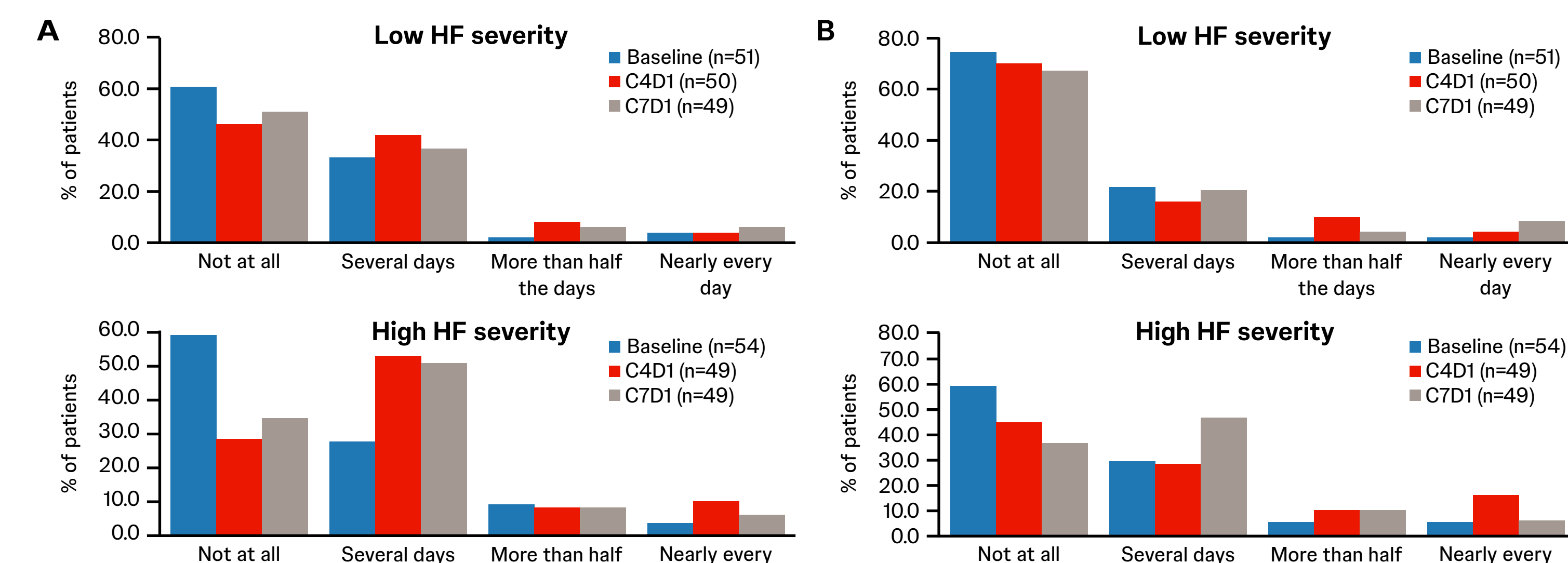
Percentages based on the number of participants who responded to PHQ-9 item "Feeling tired or having little energy" (A) or "Trouble falling asleep, or sleeping to much" (B) at each timepoint and within each subgroup, using n as the denominator.

Figure 6: Patient-reported PHQ-9 fatigue (A) and sleep disturbance (B) in the ITP ADT-naïve subgroup.



Percentages based on the number of participants who responded to the PHQ-9 item "Feeling tired or having little energy" (A) or "Trouble falling asleep, or sleeping to much" (B) at each timepoint and within each subgroup, using n as the denominator.

Figure 7: Patient-reported PHQ-9 fatigue (A) and sleep disturbance (B) in the ITP HF-emergent subgroup.



Percentages based on the number of participants who responded to the PHQ-9 item "Feeling tired or having little energy" (A) or "Trouble falling asleep, or sleeping to much" (B) at each timepoint and within each subgroup, using n as the denominator.

