Impact of Baseline Hot Flashes on Sleep Metrics During Initial Treatment in LIBERTAS Clinical Trial

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Presented by A Azad at ASCO GU; February 26–28, 2026; San Francisco, CA, USA

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KEY TAKEAWAYS

Baseline hot flashes were associated with more pronounced and persistent sleep disturbances among participants with mCSPC during the initial treatment phase of LIBERTAS, which combines apalutamide with continuous ADT. These findings suggest a mechanistic link between vasomotor symptoms and sleep disruption and raise the possibility that treatment de-escalation strategies, when clinically appropriate, may serve as a targeted approach to mitigate symptom burden and preserve patient well-being

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CONCLUSIONS

- Participants showed increased Wake After Sleep Onset and number of awakenings, and decline in sleep efficiency after initiating apalutamide + continuous ADT
- Participants with baseline hot flashes had a greater increase in Wake After Sleep Onset and number of awakenings, and greater decline in sleep efficiency vs those without baseline hot flashes; this was also observed among ADT-naïve participants
- PHQ-9 data revealed a similar pattern of sleep disturbance, highlighting subjective experiences aligned with objective sleep metrics

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INTRODUCTION

- Sleep disturbances are prevalent among patients with metastatic castration sensitive prostate cancer (mCSPC), and can substantially impair quality of life and influence therapeutic efficacy[1,2]
  - Vasomotor symptoms, particularly hot flashes, are frequently reported during hormonal therapy and may exacerbate sleep disruption
- Understanding the association between hot flashes and sleep quality has the potential to further improve patient treatment experience
- Apalutamide (APA) with continuous androgen deprivation therapy (ADT) provides patients with a rapid and deep prostate-specific antigen (PSA) decline in mCSPC; this deep PSA response is associated with improved overall survival and sustained quality of life[3,4]
- LIBERTAS, an ongoing ADT de-escalation study, is evaluating APA + intermittent ADT vs continuous ADT in participants with mCSPC who have deep PSA decline after initial treatment with APA + continuous ADT
  - ADT de-escalation in combination with APA may reduce the ADT side effect burden, including hot flashes and sleep disturbances, without loss of efficacy
- Here we evaluated the impact of baseline (BL) hot flashes on sleep during the initial 6-month treatment phase of LIBERTAS

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METHODS

- LIBERTAS (NCT05884398) is a phase 3, prospective, open-label, randomized study in participants with mCSPC (**Figure 1**)
- Participants were stratified into two groups based on severity-adjusted flash scores at baseline: No Hot Flash (score=0) and Any Hot Flash (score >0)
- Digital sleep metrics were derived from triaxial acceleration data collected via the Ametris CentrePoint Insight Watch, which participants wore on the wrist throughout the study
  - Sleep metrics were analyzed at 3 prespecified visits: BL, Cycle 4 Day 1, and Cycle 7 Day 1
  - Metrics included Wake After Sleep Onset (WASO), number of awakenings, and sleep efficiency
- Sleep/wake classification was performed using Cole-Kripke or Sadeh algorithm
- Cross-sectional comparisons of sleep metrics between groups were performed using Mann-Whitney U test
- Sleep disturbances and fatigue were also evaluated using Patient Health Questionnaire-9 (PHQ-9)

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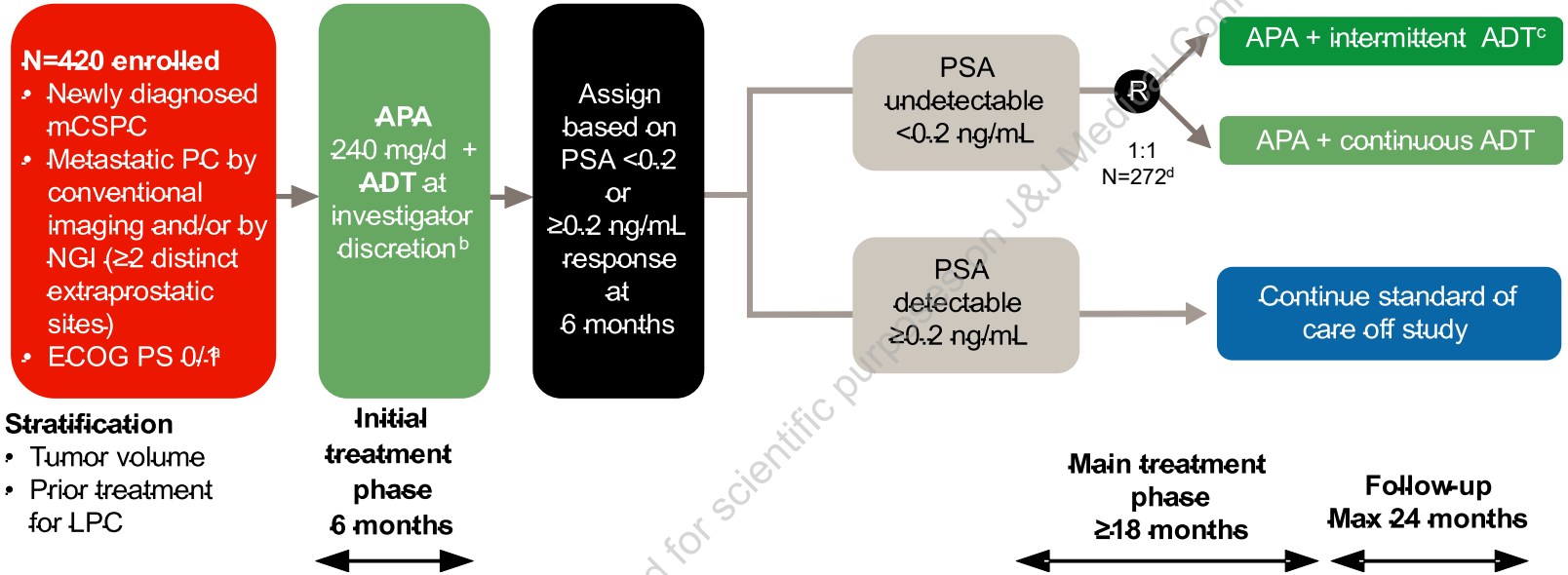
METHODS

Figure 1: LIBERTAS study design



Dual primary end points

18-month radiographic PFS rate[e]	18-month percent change in severity-adjusted hot flash score[f]

ECOG PS, Eastern Cooperative Oncology Group performance status; LPC, localized prostate cancer; NGI, next-generation imaging. [a]Participants with ECOG PS 2 or 3 were eligible for the study if the ECOG PS score was related to stable physical limitations and not related to prostate cancer or associated therapy. [b]Choice of gonadotropin hormone–releasing hormone agonist or antagonist at discretion of investigator. [c]ADT can be restarted in the APA + intermittent ADT group for participants with new or worsening cancer symptoms, PSA increase to >10 ng/mL (or return to BL level when PSA was <10 ng/mL before start of ADT), or PSA doubling time <6 months. [d]272 participants were randomized including 1 participant without assignment of randomized treatment (intent-to-treat population n=271). [e]Radiographic progression assessed using conventional imaging. [f]Evaluated with hot flash diary data.

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RESULTS

BL characteristics

- Among 420 participants enrolled in the initial 6-month treatment phase, 250 (60%) reported hot flashes at BL (**Table 1**)
- Prestudy, ADT for mCSPC was received by 65% of all enrolled participants; more participants with hot flash at BL (73%) had received ADT vs those without hot flashes at BL (54%)

Table 1: BL characteristics

	No Hot Flash at BL n=170	Any Hot flash at BL n=250
Age, years		
Median (IQR)	72 (67–76)	69 (63–75)
≥75, n (%)	57 (34)	67 (27)
Race, n (%)[a]		
White	118 (69)	179 (72)
Asian	17 (10)	22 (9)
Black or African American	15 (9)	21 (8)
Median (IQR) time from mCSPC diagnosis to initial treatment, mo	2.1 (1.4–3.2)	2.5 (1.5–3.5)
ECOG PS, n (%)		
0	129 (76)	183 (73)
1	40 (24)	65 (26)
2	1 (1)	2 (1)
Gleason score at diagnosis, n (%)[b]		
≤7	56 (33)	83 (33)
>7	109 (64)	160 (64)
Metastasis stage at diagnosis, n (%)[c]		
M0 or MX	67 (39)	79 (32)
M1	102 (60)	171 (68)
Bone metastasis at BL, n (%)	127 (75)	218 (87)
Visceral metastasis at BL, n (%)	25 (15)	45 (18)
High volume[d], n (%)	79 (46)	125 (50)
Received prior ADT for mCSPC, n (%)	92 (54)	182 (73)

IQR, interquartile range. [a]Other participants were other (n=9), multiple (n=5), and not reported/unknown (n=6) in "no hot flash at BL"; and American Indian or Alaska Native (n=2), other (n=13), multiple (n=6), and not reported/unknown (n=7) in "any hot flash at BL." [b]Missing data: "no hot flash at BL" (n=5), "any hot flash at BL" (n=7). [c]Missing data: "no hot flash at BL" (n=1). [d]Defined as either visceral metastases or ≥4 bone lesions, including ≥1 outside of the vertebral column or pelvis based on the CHAARTED criteria.[5]

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RESULTS

Actigraphy adherence

- Actigraphy adherence ranged between 90.5%–92.6% across timepoints, calculated as the percentage of time the device was worn over a 24-hour period; adherence was similar across participants with and without hot flash at BL (**Table 2**)

Table 2: Mean (SD) adherence, %

Time point	Full analysis (N=403)	No hot flash at BL (n=155)	Any hot flash at BL (n=248)
Baseline	90.5 (15.5)	90.0 (16.0)	90.8 (15.2)
Cycle 4 Day 1	92.6 (11.6)	92.9 (10.1)	92.5 (12.5)
Cycle 7 Day 1	91.5 (14.3)	91.3 (16.1)	91.6 (13.1)

SD, standard deviation.

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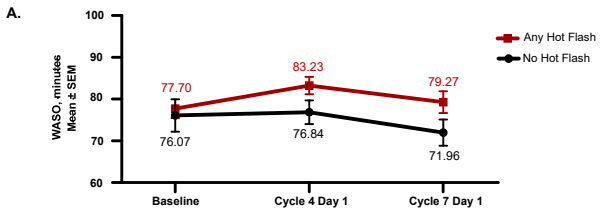
RESULTS

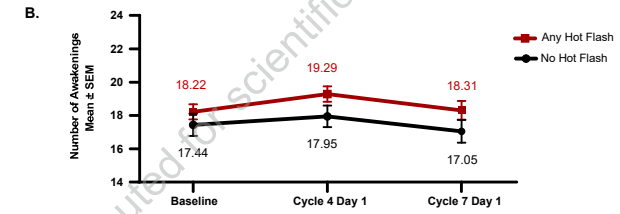
Digital sleep metrics in participants with vs without hot flashes at BL (Figure 2)

- Following the start of the initial treatment phase, all participants showed increased WASO and number of awakenings and a decline in sleep efficiency (**Figure 2**)
- Participants with hot flashes at BL experienced a significantly greater increase in WASO and number of awakenings, and a significantly greater decline in sleep efficiency compared to those without hot flashes at BL ($P<0.05$)
- By the end of the initial treatment phase, both groups trended towards BL values
  - However, the any BL hot flash group maintained a significantly higher WASO and lower sleep efficiency vs the no BL hot flash group ($P<0.05$)

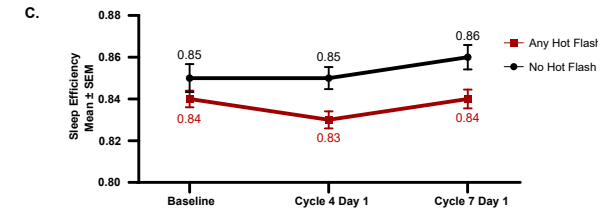
Figure 2. A) WASO, B) number of awakenings, and C) sleep efficiency in participants with vs without hot flashes at BL (all enrolled participants)



		Baseline	Cycle 4 Day 1	Cycle 7 Day 1
Any Hot Flash	n	227	214	176
	Median	72.71	79.80	73.45
	IQR	56.86–93.79	61.52–100.19	57.75–94.38
No Hot Flash	n	143	129	105
	Median	70.08	73.75	65.43
	IQR	43.93–95.41	55.30–91.73	49.57–89.17
	Wilcoxon *P*	0.135	0.028	0.042



		Baseline	Cycle 4 Day 1	Cycle 7 Day 1
Any Hot Flash	n	227	214	176
	Median	17.50	19.00	18.37
	IQR	13.71–22.17	14.81–23.62	13.72–22.71
No Hot Flash	n	143	129	105
	Median	16.40	17.29	16.25
	IQR	12.00–21.90	12.69–21.73	12.12–20.83
	Wilcoxon *P*	0.114	0.019	0.114



		Baseline	Cycle 4 Day 1	Cycle 7 Day 1
Any Hot Flash	n	227	214	176
	Median	0.85	0.84	0.85
	IQR	0.80–0.88	0.80–0.87	0.81–0.88
No Hot Flash	n	143	129	105
	Median	0.86	0.85	0.87
	IQR	0.80–0.90	0.82–0.89	0.84–0.89
	Wilcoxon *P*	0.080	0.012	0.025

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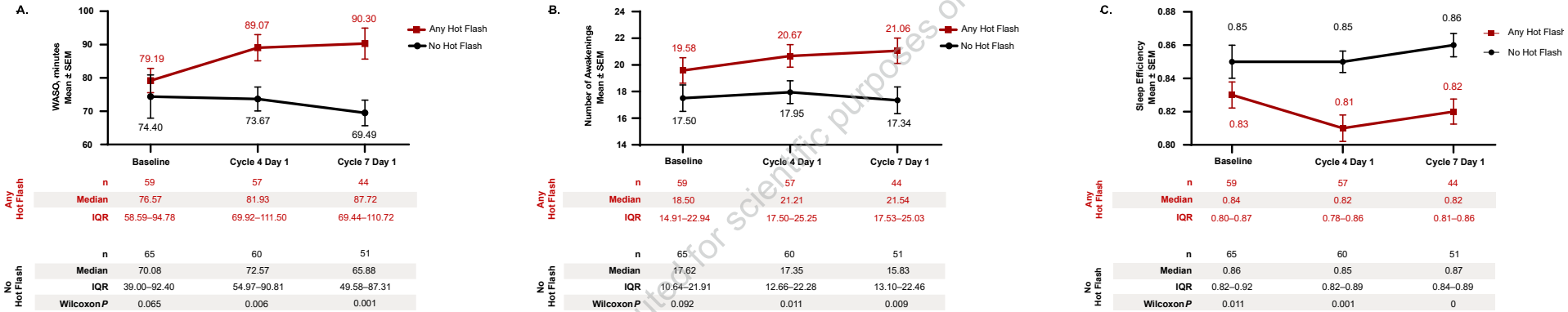
RESULTS

- Similar patterns of sleep disturbances were observed among participants who had not received prestudy ADT (**Figure 3**)
  - Among ADT-naïve participants, sleep efficiency scores at BL were lower in participants with BL flashes vs those without BL hot flashes

Figure 3. A) WASO, B) number of awakenings, and C) sleep efficiency in participants with vs without hot flashes at BL (ADT-naïve participants)



		Baseline	Cycle 4 Day 1	Cycle 7 Day 1
Any Hot Flash	n	59	57	44
	Median	76.57	81.93	87.72
	IQR	58.59–94.78	69.92–111.50	69.44–110.72
No Hot Flash	n	65	60	51
	Median	70.08	72.57	65.88
	IQR	39.00–92.40	54.97–90.81	49.58–87.31
	Wilcoxon *P*	0.065	0.006	0.001

		Baseline	Cycle 4 Day 1	Cycle 7 Day 1
Any Hot Flash	n	59	57	44
	Median	18.50	21.21	21.54
	IQR	14.91–22.94	17.50–25.25	17.53–25.03
No Hot Flash	n	65	60	51
	Median	17.62	17.35	15.83
	IQR	10.64–21.91	12.66–22.28	13.10–22.46
	Wilcoxon *P*	0.092	0.011	0.009

		Baseline	Cycle 4 Day 1	Cycle 7 Day 1
Any Hot Flash	n	59	57	44
	Median	0.84	0.82	0.82
	IQR	0.80–0.87	0.78–0.86	0.81–0.86
No Hot Flash	n	65	60	51
	Median	0.86	0.85	0.87
	IQR	0.82–0.92	0.82–0.89	0.84–0.89
	Wilcoxon *P*	0.011	0.001	0

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Impact of Baseline Hot Flashes on Sleep Metrics During Initial Treatment in LIBERTAS Clinical Trial

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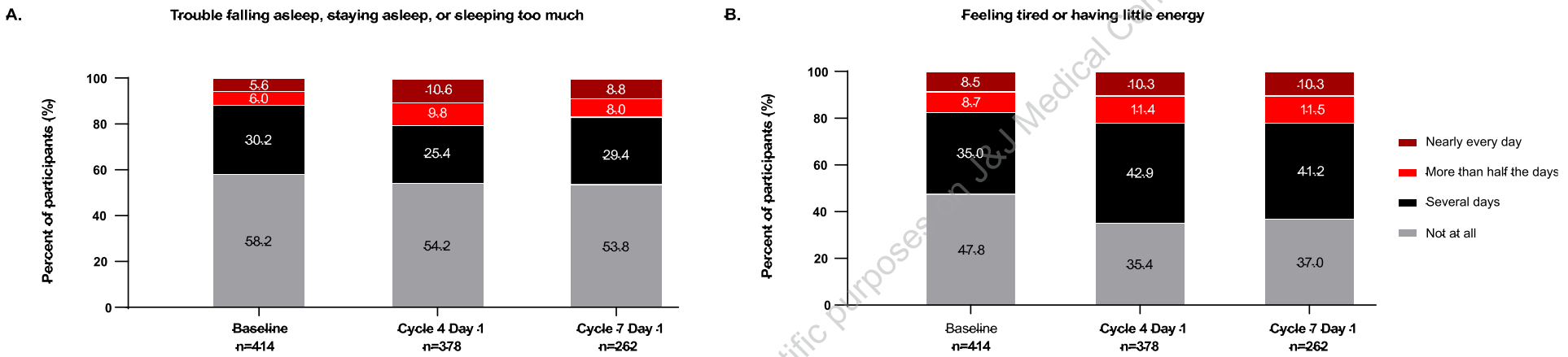
RESULTS

Figure 4: PHQ-9 scores over time: A) sleep disturbances and B) fatigue in all enrolled participants



Sleep disturbances and fatigue based on PHQ-9

- PHQ-9 data indicated heightened sleep disturbances and fatigue over the initial treatment phase in all enrolled participants (**Figure 4**), consistent with the digital sleep metric data
- Depression severity scores and Patient Global Impression of Change (PGIC) scores were stable during the initial treatment phase (**Supplemental Figure 1**)

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DISCLOSURES:

Arun Azad reports relationships/financial interest in/relative to as follows: Aculeus Therapeutics, Amgen, Astellas, AstraZeneca, Bayer, Bristol Myers Squibb, Daiichi Sankyo, Ipsen, Janssen, Merck Serono, Merck Sharp & Dohme, Novartis, Noxopharm, Pfizer, Sanofi, Telix Pharmaceuticals, Tolm.

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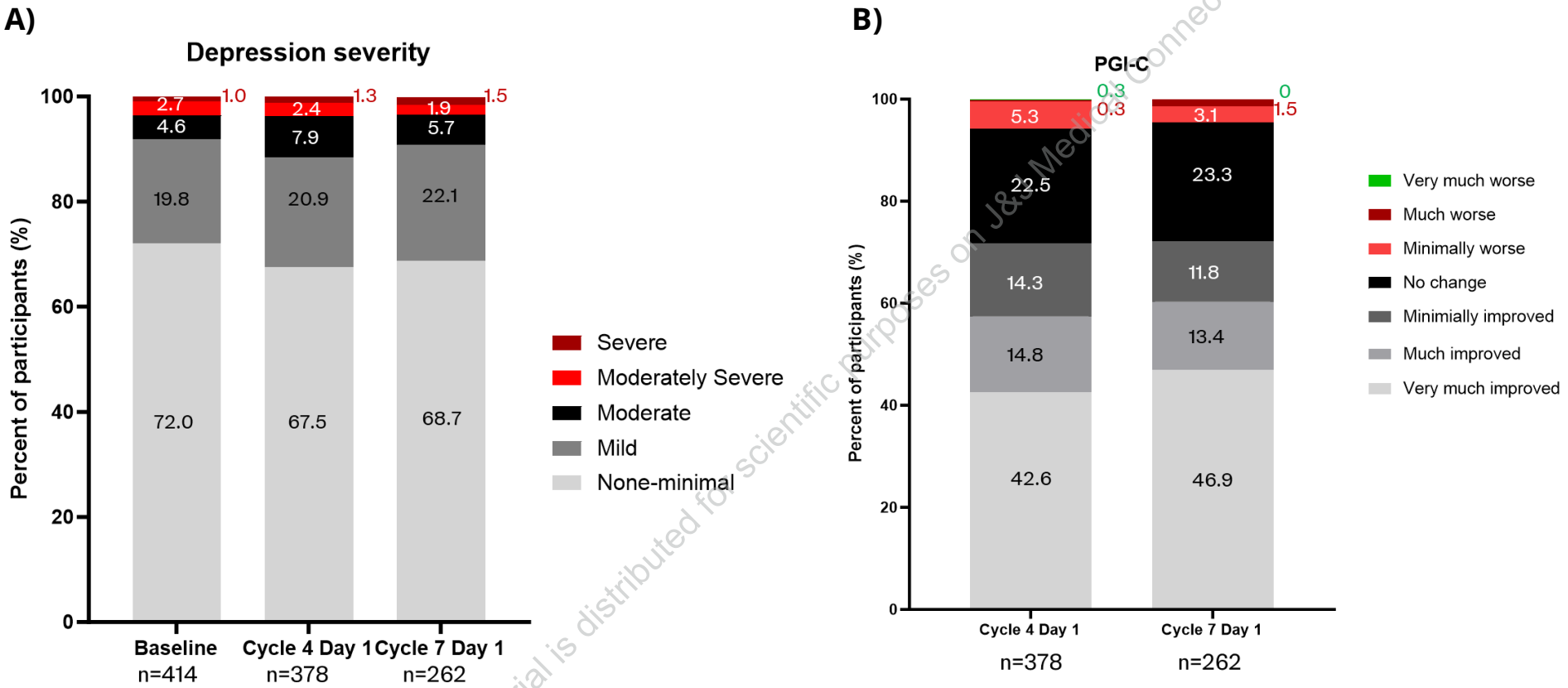
Supplementary Figure 1: A) Depression severity and B) PGI-C in all enrolled participants



Depression severity scores are based on PHQ-9. PGI-C, Patient Global Impression of Change.

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