Sleep disturbances in menopausal women with vasomotor symptoms: baseline findings from two Phase 3 studies

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INTRODUCTION

Sleep disturbances associated with menopause are common and bothersome and can **impact women's health and quality of life.**[1] However, many women do not attribute their sleep disturbances to menopause and clinicians may not ask about sleep disturbances in counselling.[1]

This analysis aims to characterize sleep disturbances among women entering the two pivotal, phase 3, OASIS clinical trials of elinzanetant, a neurokinin-1,3 receptor antagonist, for the treatment of vasomotor symptoms (VMS, also known as hot flashes) associated with menopause.

METHODS

Overall, 396 women were randomized in OASIS 1 (O1) and 400 in OASIS 2 (O2). To be eligible, women needed to be **postmenopausal and experience ≥50 moderate to severe VMS per week.** There was no requirement for severity of sleep disturbances to enter the study.

The Patient-Reported Outcomes Measurement Information System sleep disturbance short form (**PROMIS SD SF**) 8b questionnaire was administered electronically at baseline and weeks 1, 2, 3, 4, 8, 12, 16, 26, and 30 to assess severity of **sleep disturbances**. Data from baseline only are presented here.

The questionnaire consisted of eight items:

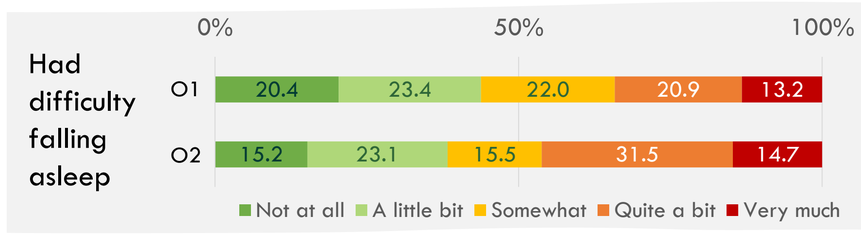
- I had difficulty falling asleep
- I had difficulty staying asleep
- My sleep was restless
- My sleep was refreshing
- I got enough sleep
- My sleep quality was…
- I was satisfied with my sleep
- I had trouble sleeping...

Each item was scored on a 5-point scale. Items were assessed individually or summed to yield total raw scores which were converted to total T-scores (range 28.9–76.5).[2] A PROMIS SD SF 8b total T score (SD) of 50 (10) represents the mean in a US reference population.[3] **Higher scores indicate greater severity of sleep disturbances.**

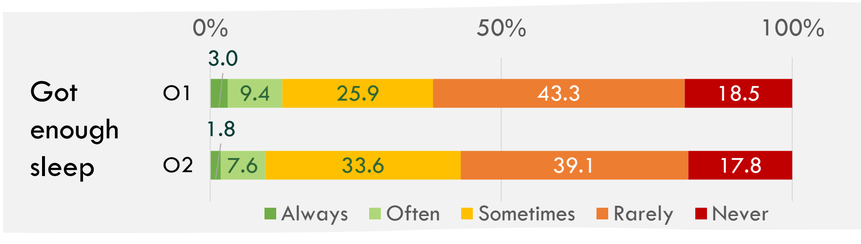
RESULTS

At baseline mean (SD) PROMIS SD SF 8b total T-scores ranged from 60.2 (7.2) to 61.7 (6.2) across O1 and O2, this reflects moderate sleep disturbances according to classification established in a US reference population[3]. Women were experiencing a mean (SD) of 13.38 (6.57) – 16.16 (11.15) moderate to severe hot flashes per day at baseline across the two studies.

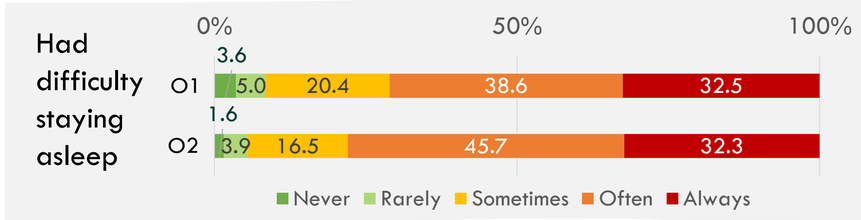
Percentage of participants in OASIS 1 (N=363) & OASIS 2 (N=381) with PROMIS SD SF 8b data available at baseline who:



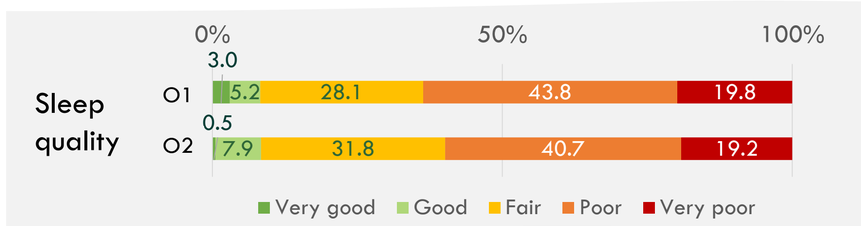
34 – 46%
Had 'quite a bit' or 'very much' difficulty falling asleep



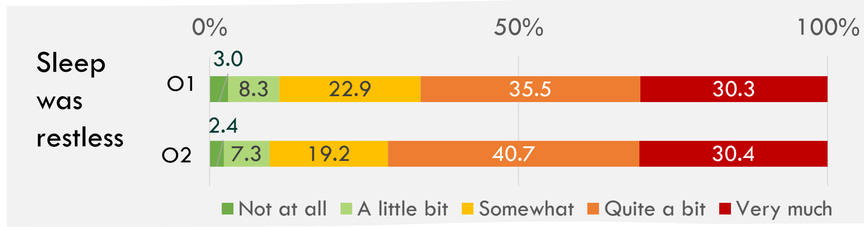
57 – 62%
'rarely' or 'never' got enough sleep



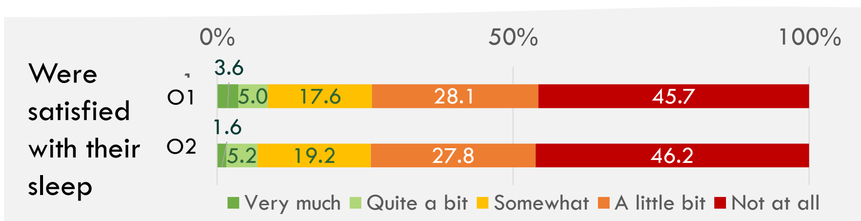
71 – 78%
'Often' or 'always' had trouble staying asleep



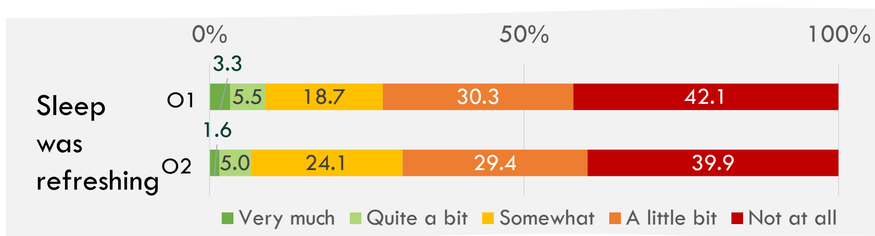
60 – 64%
had 'poor' or 'very poor' quality sleep



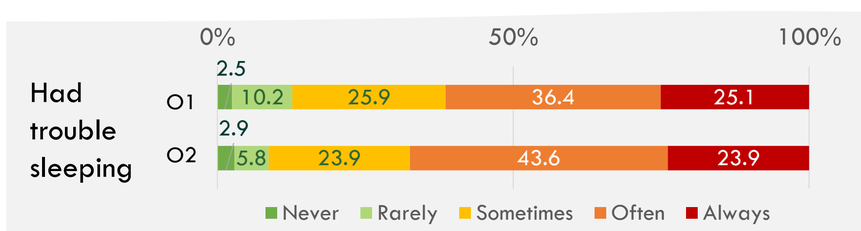
66 – 71%
reported their sleep was 'quite a bit' or 'very much' restless



74%
were 'a little bit' or 'not at all' satisfied with their sleep



69 – 73%
reported their sleep was 'a little bit' or 'not at all' refreshing



62 – 68%
'often' or 'always' had trouble sleeping

CONCLUSIONS

Despite not being selected from a population with sleep disturbances for the OASIS clinical trials, participants presented with a considerable magnitude of sleep disturbances at baseline.

Most women reported trouble sleeping and staying asleep, their sleep was restless and not refreshing and many reported poor quality and unsatisfactory sleep.

These findings are in concordance with others that have found night-time awakenings, wakefulness after sleep onset, poor quality and insufficient or non-restorative sleep as the most common manifestations of sleep disturbances associated with menopause.[1]

These data highlight the high degree of sleep disturbances among postmenopausal women with VMS and support the need for greater awareness and recognition of sleep disturbances and the need to address them in this population.

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REFERENCES

1. Maki PM, et al. Menopause 2024; in press; 2. Lan Yu, et al. Behav Sleep Med 2011;10:6 – 24; 3. Health Measures. PROMIS score cut points. Accessed (May 21, 2024). https://www.healthmeasures.net/score-and-interpret/interpret-scores/promis/promis-score-cut-points

DISCLOSURES

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